

# BROWN UNIVERSITY

## CONSENT FOR RESEARCH PARTICIPATION:

Parent Consent Form for Teen

Brief Individual and Parent Interventions for Substance Use in Truant Adolescents (Version 6; 2/5/20)

#### **KEY INFORMATION**

You and your teenager are being asked to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: We are trying to see if counseling sessions with both a teen and a parent will help teenagers who have been exposed to other teens smoking marijuana or may have begun to experiment with using marijuana and are also truant from school.
- PROCEDURES: Today, your teen will be asked to complete questionnaires, and have a videotaped discussion relating to marijuana and other substance use and school. Urine will be collected from your teen for drug screening. In one week you will both return and you will be randomly chosen to either: 1) meet separately with a counselor to discuss the results of the questionnaires and videotape discussion you complete today; or 2) meet separately with a counselor to review educational materials about marijuana and other substance use and school attendance. This meeting will be audio-recorded. Your teen will return three other times to complete the same questionnaires and the videotaped discussion that you will complete today.
- TIME INVOLVED: This study starts today and involves 4 more sessions, in one week, and then in 3, 6, and 12 months from now. The first baseline session will take about 2 hours (one hour and 15 minutes for the parent assessment, 1 ½ hours for the teen assessment and 20 minutes for the video-taped family discussion), and each follow-up session will take about 1 hour of your time.
- COMPENSATION: Your teen will receive \$100 for completing questionnaires at the baseline session and \$50 each time that he/she completes questionnaires over the next year (total amount \$250 if he/she completes all 4 interviews).
- RISKS: Your teen may feel uncomfortable about the sensitive topics discussed or being videotaped, and there is a chance of loss of privacy and confidentiality affecting your teenager's reputation and employment
- BENEFITS: There are no direct benefits for participating in this research study. Your teen may learn about ways to cut down or stop smoking marijuana and to improve school attendance.

## 1. Researcher:

This researcher is being conducted by Anthony Spirito, PhD. He may be contacted at anthony\_spirito@brown.edu or 401-444-1929.

## 2. What is the study about?

Your teen is being asked to participate in this study because he/she is involved with the courts due to truancy and has reported marijuana use. The study starts today and involves another meeting about a week from now and three more meetings 3, 6, and 12 months from now. We



are trying to see if a counseling session with both teens and a parent will help court-involved teenagers who have been using marijuana and improve school attendance. This research is sponsored by the National Institutes of Health.

**Optional interview:** We are also offering parents and teens the option of completing an additional one hour interview regarding how to **prevent** teens from using opioids and prescription pain killers that are not prescribed to them. This interview will be conducted at a time convenient to you and your teen. We will be asking questions to both you and your teen in separate interviews. The questions we will be asking include things like: "What do you know about opioid use among teenagers? Have you ever talked with your teen about using opioids? If you were going to develop a program to help parents learn about the potential risks and ways to prevent adolescent opioid use, what would that look like?" Both you and your teen will be compensated \$50 for the time it takes to complete these interviews.

Yes, I am interested in setting up a time for my teen to complete this interview. (Initial here if yes)
No, I am not interested in having my teen take part in this interview. (Initial here if no)

# 3. What will my teen be asked to do?

Today, your teenager will also be asked to complete an interview and several questionnaires about his/her marijuana and alcohol use, attitudes about marijuana use, and his/her friends' use of marijuana. Your teen will also be asked to provide a urine drug screen test. You will not be able to see your teen's responses to these questionnaires or the urine drug screen. It will take about 90 minutes for your teen to complete his/her measures. If your teen appears under the influence of alcohol or drugs, we will reschedule a time to complete the questionnaires.

After completing the questionnaires, you and your teenager will have a 20-minute meeting to discuss everyday issues that occur in homes with teenagers, such as curfew, grounding, school, chores, going out with friends, as well as discussions about your beliefs regarding school attendance, drinking and marijuana use. This discussion will be videotaped. The video tapes will be erased at the end of the project. We will review your videotapes and make ratings on the way that you and your teen discuss these different beliefs.

In total, your teen's visit today should take about 2 hours.

After completing the videotaped discussion, families will be randomly assigned into one of 2 groups. (Note: Randomization means that you are put into a group by chance. It is like flipping a coin). If you are assigned to one group, your family will come back in about a week and both you and your teen will meet separately with a counselor to discuss the results of the questionnaires you complete today. You will also discuss ways for your teen to reduce or stop using marijuana and improve school attendance.

If you are assigned to the other group, your family will also come back in one week and both you and your teen will meet separately with a counselor to review educational materials about marijuana and other substance use.

This second session should take about 1 hour.



Regardless of which group you are in, 3, 6, and 12 months from now, your teen will come back here to complete the same forms you are going to complete today. Your teen will again be asked to complete a urine drug screen. The visits at 3, 6 and 12 months should take 90 minutes. At the 3-month visit, your teen, regardless of the group you are assigned to, will also review the topics you discussed in the first meeting with the counselor.

We will also collect information from your child's court file, including: information about your child's involvement with the Rhode Island Family Court, such as number of charges, types of past charges, and whether they receive any new charges during the course of the study; and if applicable, data from your child's initial mental health screening at the Rhode Island Family Court; and previous mental health treatment referrals.

# 4. Will your teen be paid?

Your teen will receive \$100 for answering questionnaires today and \$50 when he/she comes back in 3, 6, and 12 months. If your teen completes all four of these interviews, he/she will receive \$250 in total. If you and your teen need transportation to attend any of these sessions, we will arrange it.

TABLE 1.	All parents	All teens		
Baseline Assessment [Parent & teen each receive \$100]	Parent assessment (about 1 hour)  Demographic form Parent questionnaires on teen substance use, parenting, and related topics	Teenager assessment (about 1 ½ hours)  Demographic form  Adolescent interview  Adolescent questionnaires on substance use and other related topics including school attendance  Urine drug screen		
	Family assessment (about 20 min): Observed interactions between parent and teen			
Counseling Session [1 week after baseline assessment]	Parents and teens are randomly assigned to receive either:  1) Separate meetings with a counselor to discuss the results of the questionnaires and family assessment completed at baseline (1 hour), and to receive texts on parenting for 6 weeks, or  2) Separate meetings with a counselor to review educational materials about marijuana and other substance use (1 hour).			
3-Month Assessment [Parent & teen each receive \$50] and 3-Month Booster	Parent assessment (about 30 min)  Parent questionnaires on teen substance use, parenting, and related topics  Teenager assessment (about 30 min)  Adolescent interview  Adolescent questionnaires on substance use and other related topics  Urine drug screen			
Session	Observed interactions between parent sment and the observed interactions and teens will have separate meetings to			



	review the material discussed in the counseling session (this will take about 30 minutes)
6 and 12	Parents and teens complete assessments almost identical to the baseline
Month	session (about 90 minutes)
Assessments	
[Parent & teen	
each receive	
\$50]	

# 5. What are the risks?

The questionnaires that your teenager will answer are commonly used in research and clinical practice. It is possible that your teenager may become upset or experience emotional distress when answering questions about his/her substance use, and when being videotaped discussing house rules related to substance use. Your teenager may choose not to answer any questions and may stop his/her participation in the study at any time. He/she may also request to speak with Dr. Spirito, a licensed clinical psychologist, at any time if he/she becomes upset or experiences emotional distress. Your teenager will be asked sensitive information about a number of behaviors including alcohol and marijuana use and other problem behaviors. There is a risk of loss of privacy or confidentiality of these sensitive data, which could affect your teenager's reputation and employability, and could potentially lead to adverse legal consequences if disclosed. We take this risk very seriously, and we will take steps to protect your and your adolescent's information. We describe the steps we will take in Section 7 "How will my information be protected?" below.

# 6. What are the benefits?

This study may not benefit your teen personally. However, by answering these questions and taking part in the family interview, teenagers may have the opportunity to learn more about substance use, family interactions, and ways to improve communication.

There is a possibility that participating in this research study may positively affect your teen's relationship with Rhode Island Truancy Court or Family Court by satisfying concerns that your teen should talk to someone about marijuana use and school attendance. However, this cannot be guaranteed and the same positive effect may occur by arranging for further counseling about marijuana use and school attendance outside of being in this study.

## 7. How will my information be protected?

All of your teenager's records from this study will be treated as private records. The records will be protected according to the rules of Brown University. Your teenager's name will not be on the questionnaires. During audio or video assessments, you and your teen will be asked to use your first names only. All information will be identified only by a code number, not your names. Information collected during the assessments, including video recordings, and counseling procedures are treated as confidential and will not be shared. Records will be kept in a locked filing cabinet in a locked office at Brown University. All audio and video recordings will be stored on a secure server or a password protected, external hard drive stored in a locked cabinet. Only researchers working on this study will have access to the information provided by you. We will not share any of the information your teen report with the courts. There are times when other researchers may ask to see the responses of teens in the study. If this occurs, we will not release your teen's name or any other information that could identify your teen.



All laptop computer data collected electronically will be stored on a secure server. All laptop computer data as well as any paper data that is entered into a computer database will be accessible only to research staff members and will be password protected. All paper data will be stored in locked file cabinets behind locked doors and will only be accessible to research staff members. Only research staff who have direct contact with participant families will have access to participant identities.

There are times when the law might require Brown University to release your teenager's information without either of your permission. To give you some examples, if your teen discloses information that makes us suspect abuse or neglect of your children, or if your teenager reports any information that makes us suspect that she or he has been the victim of abuse or neglect, State Law requires that we report that information to the Department of Children, Youth and Families (DCYF). If your teenager discloses information that makes us concerned that he/she could harm himself/herself or harm others, we will be required to share that information with a licensed clinician.

Participation in research may cause a loss of privacy. In this study, your child's will be asked about marijuana use and other sensitive activities. We will do everything we can to keep others from learning about your child's participation in the research. To help keep your child's information private and confidential, we have obtained a Certificate of Confidentiality from the federal agency giving us money for this study, the National Institutes of Health (NIH) and the Department of Health and Human Services, (DHHS). This certificate does not imply that officials of NIH or DHHS approve or disapprove of the project. With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose information that may identify you and your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of the Department of Health and Human Services for the purpose of audit or evaluation. You should understand that a Confidentiality Certificate does not prevent you or your teen from voluntarily releasing information about the study or your involvement in this research. This means that your family must also actively protect your privacy.

Certificates of Confidentiality protect participants from forced disclosure of identifying information but do not prevent the researchers from disclosing voluntarily, without your consent, information that would identify your child as a participant in the research project under circumstances in which the researchers learn about serious harm to your child or someone else. Examples of such circumstances might be evidence of child abuse or a participant's threatened violence to self or others; or, voluntary disclosure of information by researchers if the researcher feels the information may jeopardize the security of the participant, that of others or the courthouse facility. If the researchers learn about serious harm to your child, or someone else, they would take steps to protect the person or persons endangered even if it required telling authorities such as the Department of Children, Youth, and Families.

A description of this clinical trial will be available on http://www.Clinicaltrials.gov, as required by U.S. Law. This Website will not include information that can identify your teen. At most, the Website will include a summary of the results. You can search this Website at any time.

Payment for participating in this study will be made using ClinCard, a pre-paid Mastercard that works like a debit card. We will give you the card. You will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University



studies that use ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from your study coordinator for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn \$600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will ask for your social security number to correctly identify you in the payment system and send you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating. If your card is lost or stolen, please call the study coordinator for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

# 8. Are there any alternatives to this study?

If your teenager does not choose to participate in this study, it will not affect your teen's case or any of your teen's court proceedings. You can obtain other services recommended by the court or seek them out on your own.

## 9. What if I want to stop?

The decision whether to allow your teenager to be in this study is entirely up to you and your teenager. Participation is voluntary. Also, if you decide now to allow your teenager to participate, you will be able to change your mind later and withdraw from the study. There will be no penalty if you decide not to allow your teenager to be in the study or withdraw from the study later. If the researcher feels it is in your teenager's best interest, they may choose to end your family's participation in this study at any time prior to completion of the study. The researcher will provide you with additional information as it becomes available, which may affect your decision to continue in the research study. Decision to participate will not affect your teen's case or any court proceedings.

## 10. Who can I talk to if I have questions about this study?

If you have questions, you can email or call\_Anthony Spirito, PhD. He may be contacted at anthony spirito@brown.edu or 401-444-1929.

# 11. Who can I talk to if I have questions about my rights as a participant?

If you or your teen have any complaints about your participation in this study, or would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Human Research Protection Program anonymously, if you wish, at (401) 863-3050 or toll-free at (866) 309-2095.



12. Consent to participate
Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Teen participant's Signature and Date	1	PRINTED NAME
Participant's Signature and Date	1	PRINTED NAME
Research Staff Signature and Date	1	PRINTED NAME