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CONSENT FOR RESEARCH PARTICIPATION

Adolescents with Substance Use Disorders Transitioning from Rosecrance Residential Treatment to the Community: Improving Outcomes via a Computer Assisted Parenting Program

Version Date: October 3, 2018

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- **PURPOSE:** The study is about testing new ways to support parents of adolescents in residential substance use treatment.
- **PROCEDURES:** You will be asked to answer questions about your communication with your teenager and will complete a 30-minute observed discussion with your teenager today. Your teenager will be asked to complete similar questionnaires and an interview about their substance use, mental health, treatment, and justice system involvement. After today's assessment, you will be randomly assigned to either Rosecrance services as usual or Rosecrance services plus a parent support program, which includes up to four optional remote parent coaching sessions, a computerized parenting program, daily parenting text messages, and a private online parent forum. At three additional times, you and your teen will be asked to complete assessments identical to the one you will complete today by phone. We will also ask your opinions about the research program and will ask your teen to provide a urine sample.

TIME INVOLVED: The study will take you up to 9.5 hours (5.5 hours of assessment time and 4 hours of treatment time). It will take about your teenager about 6 hours over the 24-week period.

- **COMPENSATION:** You and your teenager will each receive up to \$200 for your time.
- **RISKS:** It is possible that you or your teenager may experience emotional distress when answering sensitive questions about your teen's substance use, mental health, or high-risk behavior. There is a risk of loss of privacy that could lead to legal consequences if disclosed.
- **BENEFITS:** This study may not benefit you or your teen directly. Parents will have the opportunity to learn about substance use, communication skills, and have additional support following their teen's discharge from residential treatment.
- **ALTERNATIVES TO PARTICIPATION:** You and your teenager will receive the standard treatment offered at Rosecrance Health Network regardless of your family's decision to participate in this study. Your decision to participate will not affect the treatment in any way.

1. Researcher(s):

PRINCIPAL INVESTIGATOR: Sara Becker, Ph.D. **Phone:** (401) 863-6604

2. What is this study about?

The purpose of this study is to test new ways to support parents of adolescents in residential substance use treatment. You and your teenager are being asked to take participate in this study because your teenager was admitted to residential substance use treatment at Rosecrance Health Network. This program offers extra support to parents in several ways including remote coaching sessions with a coach from Brown University, access to a computer-delivered parenting skills program, text based



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messages that provide encouragement, and access to a private online message board (available via your browser and via a smartphone app) that enables parents to ask questions and receive feedback from a licensed clinical psychologist. We expect to enroll up to 40 parent-teenager pairs from Rosecrance Health Network into this study for a total of up to 80 participants. An additional 40 parent-teenager pairs are being recruited from a residential treatment facility in Rhode Island. This study is sponsored by the a Center for Alcohol and Addictions Studies Research Excellence Award, and by a grant funded by the National Institute on Drug Abuse.

3. What will I be asked to do?

Today, you will be asked to complete questionnaires about your family, your communication with your teenager, and your rules regarding your teenager's behavior (i.e., drinking, drug use). In a separate room, your teenager will be asked to complete an interview and several questionnaires about their substance use, mental health, treatment history, involvement with the legal system, communication with you, and their understanding of household rules regarding their behavior (i.e., drinking, drug use). You and your teenager will not be able to see each other's responses to these questionnaires.

After completing the questionnaires, you and your teenager will have a 30 minute meeting to discuss everyday issues that occur in homes with teenagers, such as curfew, grounding, chores, as well as discussions about your beliefs regarding behaviors such as drinking and drug use. This discussion will be observed via phone or video conference by a research staff member and audiotaped. The audio tapes will be erased at the end of the project. In total, today's session should take 1 hour for you (30 minutes of questionnaires + 30 minutes of discussion) and 1.5 hours for your teen (60 minutes of questionnaires + 30 minutes of discussion).

This study will have two different groups of research participants. Following today's session you will be assigned to receive either Rosecrance Health Network services as usual or Rosecrance Health Network services plus a parent support program. All parents will receive Rosecrance Health Network services as usual. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. We don't know which group you will be assigned to until after you enroll in the study and the computer tells us your assignment.

If you enroll in the study and are assigned to the parent support program, you will be offered four different things. First, you will be offered a series of up to four remote parent coaching sessions from a coach based at Brown University. These sessions will be offered in addition to parenting sessions that occur as part of standard care at the Rosecrance Health Network program. Each of the coaching sessions will be by phone or video conference and will last 45-60 minutes. Your attendance of these sessions is optional. If you attend, your coach will teach you different parenting skills. Second, you will be offered unlimited access to a computerized parenting program called Parenting Wisely for 6 months. This program contains video vignettes of parents modeling different skills. Third, you will receive daily text messages providing advice and support. Finally, you will receive access to a private online parent message board where you can post questions to other parents and receive feedback from a licensed psychologist. You will receive this support for up to 6 weeks after your teen is discharged.

Your remote coaching sessions will be audio recorded. The recordings will be stored on a secure server and listened to by researchers at Brown University for supervision and training purposes. Recordings will be destroyed at the end of the project. Your usage of the Parenting Wisely computer program and parent networking forum will be also be monitored and tracked by research staff at Brown University.



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At three different timepoints following your teenager's discharge, you and your teen will complete assessments identical to the one you will complete today (questionnaires + observed discussion) by phone or video conference with researchers from Brown University. In addition, you will be asked to share feedback on your opinions of the research program. You will also be mailed three urine screen kits and asked to administer a urine screen to your teen at each timepoint. If your teen appears to be intoxicated at the assessment or you and/or your teen reports that they are intoxicated, then the study session will be rescheduled. These assessments will occur at 6 weeks, 12 weeks, and 24 weeks post discharge. Each assessment will take both you and your teen about 1.5 hours.

An overview of study activities is depicted in Table 1.

4. Will I be paid?

If you and your teenager enroll, you will receive \$40 each after today's visit. You will each receive another \$40 for completing the 6 week visit, \$40 for completing the 12 week visit, and \$50 for completing the 24 week visit. In addition, you will earn an additional \$10 each (\$20 total) every time that you administer a urine screen to your teenager and share the results with research staff (3 urine screens at 6, 12, and 24 weeks). In total, you and your teenager can earn up to \$40 each for today's initial assessment, \$50 each for the 6 week assessment, \$50 each for the 12 week assessments and \$60 each for the 24 week assessment; families can earn up to \$400 (\$200 each) for completing the study. If you leave the study early, or if we have to take you out of the study, you will be paid for visits you completed.

Some of the services your child will receive are being performed only because they are participating in this research study. Examples of these 'research only' services include the parent intervention you will be offered (summarized in the table below) which includes up to four remote parent coaching sessions, access to the Parenting Wisely computer program, personalized text messages, and access to a parent networking forum. Those services will be paid for by the study and will not be billed to you or your health insurance company.

Other services your child will receive during this research study are considered "routine clinical services" that your child would have received even if they were not in the research study. Examples are any individual or family therapy sessions as part of your adolescent's residential treatment. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

5. What are the risks?

In this study we will be asking you about your teen's alcohol and drug use and other problem behavior. Some of these questions may make you uncomfortable, or bring up unpleasant feelings or memories. Both you and your teenager may choose not to answer any questions and you may stop your participation in the study at any time. You may also request to speak with the Principal Investigator, Sara Becker, Ph.D., a licensed clinical psychologist, at any time if you become upset or experience emotional distress. There is also a risk of loss of privacy or confidentiality of these sensitive data, which could potential 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".

Some of the information collected in this study will be sent outside of Brown University. A vendor named Silent Disclosure will be responsible for sending parents text messages and providing the parent



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networking forum, and a vendor named Family Works will be responsible for providing the online Parenting Wisely program. These vendors will collect data on how often you view your text messages,

Table 1. Overview of Study Activities for All Parents and Teenagers Recruited at Rosecrance Health Network and the Additional Elements for the Parenting Wisely Program

TABLE 1.	All Parents Recruited at Rosecrance Health Network	All Teenagers Recruited at Rosecrance Health Network	Additional Elements for Parents Assigned to “Parenting Wisely”
How many?	40	40	20
Baseline Interview [Parent & teen each earn \$40]	<u>Parent assessment</u> (about 30 min) <ul style="list-style-type: none">Demographic formParent monitoring questionnaireParent communication questionnaire	<u>Teenager assessment</u> (about 1 hours) <ul style="list-style-type: none">Adolescent interviewParent monitoring questionnaireParent communication questionnaire	
	Family assessment (about 30 min): Observed interactions between parent and teen		
Treatment PRIOR to teen’s discharge	<i>Rosecrance Health Network Standard Services for Parents</i>	<i>Rosecrance Health Network Standard Services for Teenagers</i>	<ul style="list-style-type: none">Up to 2 remote parent coaching sessionsAccess to Parenting Wisely (PW) computer programPersonalized text messagesAccess to online parent board
AFTER teen’s discharge	<i>Rosecrance Health Network Standard Services for Parents</i>	<i>Rosecrance Health Network Standard Services for Teenagers</i>	<ul style="list-style-type: none">Up to 2 remote parent coaching sessionsContinued access to PW computer program, personalized text messages, and online parent board
6-Week Interview [Parent & teen each earn up to \$50: \$40 for visit + \$10 for urine screen]	<u>Parent assessment</u> (about 1 hour) <ul style="list-style-type: none">Parent monitoring questionnaireParent communication questionnaireExit interview about the programConsumer satisfaction questionnaire	<u>Adolescent assessment</u> (about 1 hour) <ul style="list-style-type: none">Adolescent interviewParent monitoring questionnaireParent communication questionnaireUrine sample	<ul style="list-style-type: none">Continued access to PW computer program, personalized text messages, and online parent board
	Family assessment (about 30 min): Observed interactions between parent and teen		
12 Week Interview	All parents and teenagers complete same assessment as the 6-week interview <i>Parent and teen each earn up to \$50 (\$40 for session and \$10 for urine screen)</i>		
24 Week Interview	All parents and teenagers complete same assessment as the 6-week interview <i>Parent and teen each earn up to \$60 (\$50 for session and \$10 for urine screen)</i>		

post messages on the online message board, and use the Parenting Wisely program: these data will be monitored by research staff. No private health information about you will be shared with these vendors except for your cell phone number. Silent Disclosure requests your cell phone number so that you can receive automated text messages providing advice and support. The text messages will not contain any sensitive health care information. No other private health information will be requested or shared outside of Brown University. We will also take steps to ensure that you and your teenager do not accidentally share potentially identifiable information with these vendors. The text messages that you receive from Silent Disclosure will be one-way messages so that you cannot send text messages back. The study Principal Investigator, Sara Becker, Ph.D., will review any messages you submit to the parent message board prior to approving their posting to ensure that you do not accidentally share any private or identifying information at any time. Finally, your study counselor will help you to sign up for the online Parenting Wisely program and online message board and will ensure that you pick an online user name that is unidentifiable.

6. What are the benefits?

This study may not benefit you or your teen personally. By answering the study questionnaires and taking part in the family interview, teenagers and their parents may have the opportunity to learn more about substance use, family interactions, and ways to improve communication. Also, parents will have the opportunity to learn new parenting skills and get additional support following their teen's discharge from residential treatment. The data collected in this study will be used to design a parenting intervention that could potentially help other families have better outcomes following their teenagers' discharge from residential substance use treatment.

7. How will my information be protected?

All of your and 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 name and your teenager's name will not be on any of the questionnaires. All information will be identified only by a code number, not your names. Information collected during the assessments and coaching sessions are treated as confidential and will not be shared.. All data collected electronically will be stored on a secure server or a password protected external hard drive. Only researchers working on this study will have access to the information provided by you.

In this study we will be audio recording the interaction tasks between you and your teenager. We will also audio record your coaching sessions. We will use a digital recorder and will store the audio recordings on a secure server. We will keep this information confidential. Recordings will be destroyed at the end of the project.

Your teenager's records from this study (research records) will be maintained separately from your teenager's medical records. If you and your teenager enroll in this study, your teenager will be asked to give us information about substance use and other illegal behavior. A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your teenager's privacy. This Certificate means that the researchers cannot be forced to disclose research information that may identify you or your child, even by court subpoena, in any federal, state, or local, civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any

compulsory legal demands for research information that would identify you or your teenager. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself, your child, or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive such information, then the researchers may not use the Certificate to withhold that information. This means that you and your family must actively protect your own privacy by not sharing information about your participation.

There are times when the law might require Brown University to release your or your teenager's information without either of your permission. To give you some examples, if you disclose 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 and Families (DCF). If you or your teenager disclose information that makes us concerned that you or your teenager are a harm to yourself/themselves or others, we will be required to share that information with a licensed clinician. Similarly, if we are concerned that your teenager may be of harm to him/herself or someone else, we will be required to share that information with a licensed clinician as well.

Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

This study is a clinical trial in which participants are randomly assigned to one or more different treatments. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

8. Are there any alternatives to this study?

If you and your teenager do not choose to participate in this study, you will receive the standard treatment offered at Rosecrance Health Network. Your decision to participate will not affect the treatment you receive at the residential facility in any way.

9. What if I want to stop?

Taking part in research is voluntary. You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with Brown University or Rosecrance Health Network will not be affected.

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

If you have any questions about your participation in this study, you can call the Principal Investigator of the program, Dr. Sara Becker at (401) 863-6604 or email parentingwisely@brown.edu.

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

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

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.

Clicking the box below confirms that you have read and understood the information in this document, you are the legal guardian of a teen between the ages of 12 years and 0 months -17 years and 6 months, and you agree to volunteer as a research participant for this study.

Parental Consent

- ☐ Yes, I would like to participate and give permission for my child to participate, have read the information in this document, and am the legal guardian of a teen between the ages of 12 and 17 years old.
- ☐ My name is _____
 - ☐ My child who I give permission to participate in this study's name is _____
- ☐ No, I do not wish to participate and do not give permission for my child to participate

[If parent selects YES to the consent item above, the following question will be shown:

Please select one box below to indicate how you would prefer to receive a copy of this consent form.

- ☐ I would prefer to receive an electronic copy by email. My email address is _____
- ☐ I would prefer to receive a paper copy by mail. My home address is _____