



**BROWN UNIVERSITY**  
**CONSENT FOR RESEARCH PARTICIPATION**  
**Computer-assisted Counseling for Marijuana Use: RCT**  
[Version 1; 1/14/19]

**KEY INFORMATION:**

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

- **RESEARCHER:** Dr. Anthony Spirito. This research is sponsored by the National Institutes of Health
- **PURPOSE:** The study is about finding new ways to help court-involved teenagers who have been using marijuana. We are studying if a brief computer program about ways to cut down or quit smoking marijuana can be helpful to teens.
- **PROCEDURES:** Today, you will be asked to complete an interview and several questionnaires about your marijuana and alcohol use, your attitudes about marijuana use, and your friends' use of marijuana as well as communication with your parent about marijuana use, and your parents' rules about your behavior such as curfews. You will be asked to complete a urine drug screen to make certain you are not intoxicated during the interview. If you are intoxicated, we will reschedule your interview for another day. In a separate room, your parent/guardian will complete questionnaires about your family, their communication with you, and their household rules. You will not be able to see each other's responses to these questionnaires.

After you are done answering the questions, you and your parent will have a 30-minute meeting to discuss everyday issues that occur in homes with teenagers, such as curfew, grounding, chores, going out with friends, and behaviors like drinking and drug use. This discussion will be videotaped. The video tapes will be erased at the end of the project.

After you complete your videotaped meeting with your parents, you will be randomly assigned into one of two study groups. Randomly means that you are put into a group by chance. It is like flipping a coin. In one study group, either today, if you would like, or in about a week, you will receive some handouts about marijuana use and teenagers.

In the other study group, either today, if you would like, or in about a week, you will come back and watch the computer program about ways to cut down or stop using marijuana. You will also be asked your opinions about the research program.

Three and six months from now, regardless of which study group you are in, you and your parent will come back here to complete the same forms you are going to complete today. You will again be asked to complete a urine drug screen to make certain you are not intoxicated during the interview.

Study staff will collect court-related information relevant to you and your involvement in 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; data from the participant's initial mental health screening at the Rhode Island Family Court, if applicable; and previous mental health treatment and referrals for mental health treatment.



# BROWN

- **TIME INVOLVED:** The study is 3 sessions long (today's session and then 3 months and 6 months from now) and will take up to 2 hours of your time at each session.
- **COMPENSATION:** You will receive \$50 for answering questionnaires at each session for your time. If you respond to our request to update your contact information in a few months, you will receive an additional \$5. You may receive \$155 in total.
- **RISKS:** When you are answering the questions, you may sometimes feel upset or experience emotional distress. You may also become upset when discussing problems with your parent and being audiotaped or videotaped while you do so. You can refuse to answer any questions you do not like. You can also stop your participation in the study at any time.

There is a risk of loss of privacy in this study including sensitive information on your alcohol and drug use. The information you share with us could affect your reputation and employability, and could lead to negative legal consequences if it were disclosed with people outside of the study. We take this risk very seriously, and we will take steps to protect your information. For example, your name and your parent's name will not be on any of the study questionnaires or materials.

- **BENEFITS:** You may not directly benefit from being in this research study.
- **ALTERNATIVES TO PARTICIPATION:** The alternative is not to participate.
- **CONFIDENTIALITY:** All of your information, including audio and video recordings, will be identified only by a code number, not your names. Any information you share with us will be stored in locked cabinets or on a secure server or a password protected, encrypted external hard drive in locked offices at Brown University.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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 you as a participant in the research project under circumstances in which the researchers learn about serious harm to yourself 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 yourself, or someone else, they would take steps to protect the person or persons endangered even if it required telling authorities.

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.

- **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.
- **CONTACT INFORMATION:** If you have any questions about your participation in this study, you can contact Dr. Anthony Spirito at (401) 444-1929 or [Anthony\\_Spirito@Brown.edu](mailto:Anthony_Spirito@Brown.edu).



- If you have ANY questions regarding this study or if there is something that is not clear, please feel free to ask the research staff member.

You will be offered a copy of this form.

Research Staff Signature and Date / PRINTED NAME



BROWN

**BROWN UNIVERSITY**  
**CONSENTIMIENTO DE LOS PADRES PARA PARTICIPAR EN UN ESTUDIO**  
**INVESTIGATIVO**

**Computer-Assisted Counseling for Marijuana Use: RCT**  
**Versión 3; 1-14-19**

**INFORMACIÓN CLAVE**

Está invitado a participar en un estudio de investigación con Brown University. Su participación es voluntaria.

- **PROPOSITO:** Estamos investigando si un programa breve de computadora, dirigido a reducir o dejar de fumar marihuana puede ser útil para los adolescentes involucrados en la corte y si un programa de computadora sobre la crianza de los hijos puede ser útil para los padres.
  - **PROCEDIMIENTOS:** Se le pedirá que complete cuestionarios personales y que tenga una discusión con su hijo adolescente sobre comportamientos como el uso de drogas. Esta discusión será grabada en video. Usted entonces será elegido al azar para participar en una de las dos opciones: 1) Mirar un video de computadora sobre crianza de los hijos y recibir mensajes de texto diarios sobre crianza de los hijos durante 6 meses, o 2) recibir folletos sobre la crianza de los hijos y el uso de marihuana en los adolescentes. Se le pedirá a su adolescente que complete una entrevista y varios cuestionarios sobre el consumo de marihuana y alcohol y otros temas relacionados con el uso de marihuana. A su adolescente también se le pedirá que proporcione una prueba de detección de drogas en orina y que tenga una discusión video grabada con usted. Su adolescente entonces será elegido al azar para participar en una de dos opciones: 1) Ver un video de computadora sobre cómo reducir o deja de usar marihuana, o 2) recibir folletos sobre el uso de marihuana.
  - **TIEMPO INVOLUCRADO:** Este estudio comienza hoy y involucra dos sesiones más. Una sesión ocurrirá en una semana, otra en 3 meses, y la última en 6 meses. Cada sesión tomará aproximadamente 2 horas de su tiempo.
  - **COMPENSACIÓN:** Recibirá \$50 por su tiempo en cada sesión (cantidad total \$150). En unos pocos meses, recibirá una solicitud para actualizar su información de contacto. Si responde a nuestra solicitud, recibirá unos \$5 adicionales.
  - **RIESGOS:** Puede sentirse incómodo en discutir temas delicados o en ser video grabado. También existe la posibilidad de que la pérdida de privacidad y confidencialidad pueda afectar la reputación y el empleo de su hijo adolescente.
  - **BENEFICIOS:** Puede aprender algunas estrategias de crianza y los adolescentes pueden aprender formas de reducir o dejar de fumar marihuana.
  - **ALTERNATIVAS A LA PARTICIPACIÓN:** Usted tiene la alternativa de no participar.
1. **Investigador:** Esta investigación está siendo conducida por: Dr. Anthony Spirito, PhD. Puede comunicarse con el escribiéndolo sobre correo electrónico a: [anthony\\_spirito@brown.edu](mailto:anthony_spirito@brown.edu), o



BROWN

llamando a 401-444-1929. Esta investigación esta patrocinada por los Institutos Nacionales de Salud.

## **2. ¿De que se trata el estudio?**

Se le pide que participe en este estudio porque su adolescente está involucrado con los tribunales. El estudio comienza hoy y incluye dos sesiones adicionales que ocurrirán en 3 y 6 meses a partir de ahora. Estamos tratando de encontrar nuevas maneras de ayudar a los adolescentes que han usado marihuana y que están involucrados en la corte.

Estamos examinando si un programa breve dirigido a reducir o dejar de fumar marihuana puede ayudar a los adolescentes. También estamos dando apoyo adicional a los padres/guardianes haciéndoles ver un programa de computadora sobre la crianza de los hijos. Usamos los resultados de este estudio para desarrollar nuevas maneras de ayudar a los adolescentes y apoyar a los padres de los adolescentes que están involucrados con los tribunales. Por lo tanto, estamos interesados en obtener las opiniones de usted y de su adolescente sobre el programa de investigación. Esta investigación esta patrocinada por los Institutos Nacionales de Salud.

## **3. ¿Qué se me pedirá que haga?**

Hoy se le pedirá a su adolescente que complete una entrevista y varios cuestionarios sobre su consumo de marihuana y alcohol, las actitudes sobre el uso de la marihuana, el uso de marihuana de sus amigos, la comunicación con usted sobre el uso de la marihuana y sus reglas en casa, como los toques de queda. A su adolescente también se le pedirá que proporcione una prueba de detección de drogas en orina. Si su hijo está intoxicado, haremos una cita nueva para completar la entrevista para otro día. La prueba de detección de drogas en orina se administrará al comienzo de cada cita para indicar el uso reciente de drogas y corroborar el auto informe.

En salas separadas, usted y su hijo llenaran cuestionarios sobre su familia, la comunicación entre ustedes y las reglas del hogar. Ustedes no podrán ver las respuestas de que cada uno en los cuestionarios. La entrevista de usted y su adolescente debe demorarse aproximadamente 1 hora para completar.

Después de completar los cuestionarios, usted y su adolescente tendrán una reunión de 20 minutos para hablar de temas cotidianos que ocurren en los hogares con adolescentes, como los toques de queda, castigos, las tareas domésticas, salidas con amigos, así como las discusiones acerca de sus creencias con respecto a comportamientos como el uso de alcohol y drogas. Esta discusión será grabada en video. Las cintas de video se borrarán al final del proyecto.

Después de completar su reunión grabada en video, serán asignados aleatoriamente a uno de dos grupos. Asignación aleatoria significa que la asignación al grupo será hecha por casualidad. Sería como lanzar una moneda. En un grupo, recibirá unos folletos con información sobre el uso de marihuana y los adolescentes.

En el otro grupo, usted volverá (hoy o en aproximadamente una semana) para ver un programa de computadora sobre diferentes habilidades parentales y para aprender a usar un programa computarizado llamado “Ser Padres con Sabiduría” (Parenting Wisely), el cual ayuda a padres a practicar sus habilidades. Su hijo adolescente verá un programa de computadora sobre maneras de reducir o dejar de usar marihuana. También recibirá un mensaje diario por un texto con consejos y apoyo para los padres de los adolescentes por seis meses máximo. Esto se hará a través de una aplicación en su teléfono.



Cuando estamos a los tres y seis meses a partir de hoy, sin importar el grupo de estudio en el que se encuentre, usted y su adolescente regresaran aquí para completar las mismas formas que va a completar hoy. A su hijo se le pedirá otra vez que complete una prueba de detección de drogas en orina. También se le pedirá su opinión sobre el programa de investigación. Esta visita debe tomar 1 ½ a 2 horas.

Vamos hacer todo lo posible para comunicarnos con usted y recordarle de estas visitas de estudio. Es por ello, que como parte de su participación en este proyecto, le pediremos su permiso para contactar a dos personas, quienes le conozcan bien, para que nos dejen saber como podemos ponernos en contacto con usted en el caso de que su información de contacto cambie y nosotros no lo podamos encontrar. Puede que utilicemos llamadas telefónicas y cartas por correo para contactar a su familia o amigos. No le informaremos a ningún otro individuo sobre la naturaleza de este estudio investigativo y no le hablaremos sobre cualquier información confidencial que nos ha dado como parte de este estudio.

Una vez finalizado el estudio, el personal del estudio eliminará la aplicación o puede eliminarla usted mismo. La mayoría de los planes de teléfono no cobran para recibir los mensajes de texto del estudio pero usted debe confirmar con su compañía de teléfono si hay cualquier cargo por recibir textos, antes de aceptar participar en este estudio.

Personal del estudio obtendrá información relevante a su adolescente y su participación en la corte de familia de Rhode Island, tales como: número de cargos, tipos de cargos anteriores, y si reciben nuevos cargos durante el curso del estudio; datos sobre la salud mental del participante de la evaluación inicial de la corte de familia de Rhode Island, si corresponde; y también de cualquier tratamiento previo de salud mental y cualquier otra referido para el tratamiento de la salud mental.

#### **4. ¿Me pagarán?**

Usted y su adolescente recibirán \$50 cada uno por responder a los cuestionarios hoy, y \$50 cada uno cuando regresen en 3 y 6 meses. Si usted y su adolescente completan las tres entrevistas recibirán \$150 en total. En unos pocos meses, recibirá una solicitud para actualizar su información de contacto. Si responde a nuestra solicitud, recibirá unos \$5 adicionales.

#### **5. ¿Cuáles son los riesgos?**

Los cuestionarios que usted y su adolescente contestaran se usan comúnmente en investigación y práctica clínica. Es posible que usted y su adolescente se molesten o experimenten estrés o problemas emocionales al responder a preguntas sobre el uso de sustancias de su adolescente y al ser grabados en video hablando de las reglas de la casa relacionadas con el uso de sustancias. Tanto usted como su adolescente pueden escoger no contestar cualquiera de las preguntas y pueden dejar de participar en el estudio en cualquier momento. También puede comunicarse con el Dr. Spirito, un psicólogo clínico licenciado, en cualquier momento en que se moleste o experimente estrés emocional. A usted y a su adolescente se le pedirá información confidencial sobre una serie de comportamientos como el consumo de alcohol y drogas y otros comportamientos problemáticos. Existe un riesgo de pérdida de privacidad o confidencialidad de esta data sensitiva, lo cual puede afectar la reputación y capacidad de encontrar empleo de su hijo(a), y puede llevar a consecuencias legales adversas si se divulga. Tomamos este riesgo muy en serio y tomaremos medidas para proteger la información de su adolescente y usted. Describimos los pasos que tomaremos en la Sección 8 "Confidencialidad" a continuación.



Alguna de la información obtenida en este estudio será enviada a proveedores fuera de Brown llamados “Silent Disclosure y Family Works”. “Silent Disclosure” será responsable de enviar mensajes de texto a los padres, y “Family Works” será responsable de ofrecerle el programa “Ser Padres con Sabiduría”. Estos proveedores recopilarán datos sobre la frecuencia en que vez tus mensajes de texto y utilizas el programa “Ser Padres con Sabiduría”: estos datos serán monitoreados por el personal de la investigación. Ninguna información privada sobre su salud será compartida con estos proveedores excepto su número de teléfono celular. “Silent Disclosure” solicita su número de teléfono celular para que pueda recibir mensajes de texto ofreciéndole consejo y apoyo de una forma automatizada. Los mensajes de texto no tendrán ninguna información de atención médica privada. Ninguna otra información privada de salud será solicitada o compartida fuera de Brown. Estos mensajes se enviarán utilizando una aplicación que descargamos en su teléfono.

## **6. ¿Cuales son los beneficios?**

Quizás este estudio no le puede beneficiar a usted o a su adolescente personalmente. Pero, al responder a estas preguntas y participar en la entrevista familiar, los adolescentes y sus padres pueden tener la oportunidad de aprender más sobre el uso de la marihuana, las interacciones familiares y las maneras de mejorar la comunicación. Además, los padres tendrán la oportunidad de aprender nuevas habilidades parentales y recibir apoyo adicional. También, esperamos que este estudio nos ayude a diseñar un programa de crianza para ayudar a otras familias a tener mejores resultados.

## **7. ¿Hay alguna alternativa para este estudio?**

Si usted y su adolescente eligen no participar en este estudio, esto no tendrá consecuencia en el caso de su hijo/a o cualquiera de los procedimientos de la corte de su adolescente.

## **8. ¿Cómo se protegerá mi información?**

Todos los expedientes que usted y su adolescente hagan para este estudio se considerarán registros confidenciales. Su nombre y el nombre de su adolescente no estará en los cuestionarios. Durante las evaluaciones de audio o video, se le pedirá que utilice solo sus nombres primeros. Toda la información será identificada sólo por un número de código, no por sus nombres. La información recolectada durante las evaluaciones, incluyendo las grabaciones de video y los procedimientos de terapia, se tratan como confidenciales y no se compartirán. Los registros serán guardados en un archivador cerrado en una oficina cerrada en la Universidad de Brown. Todas las grabaciones de audio y video se almacenarán en un servidor seguro o en un disco duro externo protegido con contraseña. Sólo los investigadores que trabajan en este estudio tendrán acceso a la información proporcionada por usted.

Hay veces en que la ley puede requerir que la Universidad de Brown divulgue su información o la de su hijo/a sin su permiso. Para darle algunos ejemplos, si revela información que nos hace sospechar abuso o negligencia de sus hijos, o si su adolescente nos ofrece cualquier información que nos hace sospechar que el o ella ha sido víctima de abuso o negligencia, la Ley Estatal nos requiere que reportemos esa información al Departamento de Niños, Jóvenes y Familias (DCYF). Si usted o su hijo adolescente nos dejan saber de información que nos da razón por pensar que se pueden hacer daño a uno mismo o a otras personas, estaremos obligados a compartir esa información con un psicólogo licenciado. Del mismo modo, si nos preocupa que su





BROWN

hijo adolescente se pueda ser daño a sí mismo o a otra persona, estaremos obligados a compartir esa información con un psicólogo

licenciado también.

La participación en la investigación puede causar una pérdida de privacidad. En este estudio, se le preguntará a usted y a su adolescente sobre el uso de drogas y otras actividades delicadas. Haremos todo lo posible para evitar que otras personas aprendan sobre su participación y la participación de su hijo en el estudio. Para mantener su información privada y confidencial, hemos obtenido un Certificado de Confidencialidad de la agencia federal que nos da dinero para este estudio, los Institutos Nacionales de Salud (NIH) y el Departamento de Salud y Servicios Humanos (DHHS). Este certificado no implica que los funcionarios del NIH ni DHHS aprueben o desapruében el proyecto. Con este Certificado, los investigadores no pueden ser forzados (por ejemplo, mediante una citación judicial) a revelar información que pueda identificarlo a usted o a su adolescente en cualquier procedimiento civil, penal, administrativo, legislativo u otro procedimiento federal, estatal o local. No obstante, la revelación será necesaria, a petición del Departamento de Salud y Servicios Humanos (DHHS), para fines de auditoría o evaluación. Usted debe entender que un Certificado de Confidencialidad no le impide a usted o a un miembro de su familia divulgar voluntariamente información sobre el estudio o su participación en esta investigación. Esto significa que usted y su familia también deben proteger activamente su privacidad.

Los certificados de confidencialidad protegen a los participantes de la divulgación forzada de información de identificación, pero no impiden que los investigadores divulguen voluntariamente, sin su consentimiento, información que identifique a su adolescente como participante en el estudio de investigación bajo circunstancias en las que los investigadores aprendan sobre daño grave a su adolescente o alguien más. <sup>[SEP]</sup> Ejemplos de tales circunstancias pueden ser la evidencia de abuso infantil o la amenaza de violencia de un participante a sí mismo o a otros; o revelación voluntaria de la información por los investigadores si el investigador siente que la información puede poner en peligro la seguridad del participante, de otros o de las instalaciones del tribunal. Si los investigadores aprenden sobre el daño serio a su hijo/a, o a algún otro, tomarían las medidas para proteger a la persona o a las personas amenazadas incluso si requeriría decirles a autoridades tales como DCYF. <sup>[SEP]</sup>

Una descripción de este estudio clínico estará disponible en <http://www.clinicaltrials.gov>, como lo requiere la ley de los Estados Unidos. Esta pagina de internet no tendrá información que pueda identificarlo. Como máximo, esta pagina de internet incluirá un resumen de los resultados. Puede buscar esta pagina de internet en cualquier momento.

## 9. ¿Si quiero parar?

La decisión de permitir que su hijo adolescente participe en este estudio depende totalmente de usted y su adolescente. La participación es voluntaria. Además, si ahora decide permitir que su adolescente participe, podrá cambiar su mente más tarde y retirarlo del estudio. No habrá penalidad si usted decide no permitir que su adolescente esté en el estudio o que se retire del estudio más tarde. Si el investigador siente que es en el mejor interés de su adolescente, puede optar para terminar la participación de su familia en este estudio en cualquier momento antes de terminar el estudio. Si surge nueva información que lo haga cambiar de opinión sobre si quiere que su hijo(a) permanezca en el estudio, el investigador compartirá esta información con usted lo antes posible. La decisión de participar no afectará el caso de su adolescente ni ningún procedimiento judicial.





BROWN

**10. ¿Con quién puedo hablar si tengo preguntas sobre este estudio?**

Si tiene alguna pregunta sobre este estudio, puede comunicarse con el Dr. Anthony Spirito al (401) 444-1929 o por correo electrónico: [Anthony\\_Spirito@Brown.edu](mailto:Anthony_Spirito@Brown.edu)

**11. ¿Con quién puedo hablar si tengo preguntas sobre mis derechos como participante?**

Si tiene alguna queja o duda sobre su participación en el estudio de investigación o sobre los derechos de las personas que deciden participar en estos estudios, puede llamar al Programa de Protección de Investigaciones Humanas al (401) 863-3050 o llame sin cargo al (866) 309-2095.

**12. Consentimiento para participar**

Su firma a continuación muestra que ha leído y ha entendido la información en este documento, y que acepta ser participante en esta investigación.

Se le ofrecerá una copia de este formulario.

---

Firma del participante y fecha / Nombre en letra de molde

---

Firma del personal de investigación y fecha / Nombre en letra de molde



**BROWN UNIVERSITY**  
**ASSENT FOR RESEARCH PARTICIPATION**  
**Computer-assisted Counseling for Marijuana Use: RCT**  
[Version 2; 1/14/19]

**KEY INFORMATION:**

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

- **RESEARCHER:** Dr. Anthony Spirito. This research is sponsored by the National Institutes of Health
- **PURPOSE:** The study is about finding new ways to help court-involved teenagers who have been using marijuana. We are studying if a brief computer program about ways to cut down or quit smoking marijuana can be helpful to teens.
- **PROCEDURES:** Today, you will be asked to complete an interview and several questionnaires about your marijuana and alcohol use, your attitudes about marijuana use, and your friends' use of marijuana as well as communication with your parent about marijuana use, and your parents' rules about your behavior such as curfews. You will be asked to complete a urine drug screen to make certain you are not intoxicated during the interview. If you are intoxicated, we will reschedule your interview for another day. In a separate room, your parent/guardian will complete questionnaires about your family, their communication with you, and their household rules. You will not be able to see each other's responses to these questionnaires.

After you are done answering the questions, you and your parent will have a 30-minute meeting to discuss everyday issues that occur in homes with teenagers, such as curfew, grounding, chores, going out with friends, and behaviors like drinking and drug use. This discussion will be videotaped. The video tapes will be erased at the end of the project.

After you complete your videotaped meeting with your parents, you will be randomly assigned into one of two study groups. Randomly means that you are put into a group by chance. It is like flipping a coin. In one study group, either today, if you would like, or in about a week, you will receive some handouts about marijuana use and teenagers.

In the other study group, either today, if you would like, or in about a week, you will come back and watch the computer program about ways to cut down or stop using marijuana.

Three and six months from now, regardless of which study group you are in, you and your parent will come back here to complete the same forms you are going to complete today. You will again be asked to complete a urine drug screen to make certain you are not intoxicated during the interview. You will also be asked your opinions about the research program.

Study staff will collect court-related information relevant to you and your involvement in 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; data from the participant's initial mental health screening at the Rhode Island Family Court, if applicable; and previous mental health treatment and referrals for mental health treatment.

- **TIME INVOLVED:** The study is 3 sessions long (today's session and then 3 months and 6 months from now) and will take up to 2 hours of your time at each session.



# BROWN

- **COMPENSATION:** You will receive \$50 for answering questionnaires at each session for your time. You may receive \$150 in total.

- **RISKS:** When you are answering the questions, you may sometimes feel upset or experience emotional distress. You may also become upset when discussing problems with your parent and being audiotaped or videotaped while you do so. You can refuse to answer any questions you do not like. You can also stop your participation in the study at any time.

There is a risk of loss of privacy in this study including sensitive information on your alcohol and drug use. The information you share with us could affect your reputation and employability, and could lead to negative legal consequences if it were disclosed with people outside of the study. We take this risk very seriously, and we will take steps to protect your information. For example, your name and your parent's name will not be on any of the study questionnaires or materials.

- **BENEFITS:** You may not directly benefit from being in this research study.
- **ALTERNATIVES TO PARTICIPATION:** The alternative is not to participate.
- **CONFIDENTIALITY:** All of your information, including audio and video recordings, will be identified only by a code number, not your names. Any information you share with us will be stored in locked cabinets or on a secure server or a password protected, encrypted external hard drive in locked offices at Brown University.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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 you as a participant in the research project under circumstances in which the researchers learn about serious harm to yourself 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 yourself, or someone else, they would take steps to protect the person or persons endangered even if it required telling authorities.

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.

- **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.
- **CONTACT INFORMATION:** If you have any questions about your participation in this study, you can contact Dr. Anthony Spirito at (401) 444-1929 or [Anthony\\_Spirito@Brown.edu](mailto:Anthony_Spirito@Brown.edu).
- **YOUR RIGHTS:** 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](mailto:IRB@Brown.edu).
- **CONSENT TO PARTICIPATE:** Your mom, dad, and/or guardian know about this study, and they think it is OK for you to participate. If you want to be in this study, you can tell the research



# BROWN

staff member and sign below. If you do not want to be in the study, it is OK to say no. Your parent will not be told that you said no. You can stop being in the study any time you want to, and nobody will be upset with you. Your decision to participate in this study will not affect your case or any court proceedings.

If you have ANY questions regarding this study or if there is something that is not clear, please feel free to ask the research staff member.

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.

---

Participant's Signature and Date                      /                      PRINTED NAME

---

Research Staff Signature and Date                      /                      PRINTED NAME



BROWN

**BROWN UNIVERSITY**  
**PARENT CONSENT FOR RESEARCH PARTICIPATION**  
**Computer-assisted Counseling for Marijuana Use: RCT**  
**Version 3; 1-14-19**

**KEY INFORMATION**

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

- **PURPOSE:** We are studying whether a brief computer program about ways to cut down or quit smoking marijuana can be helpful to teens involved in the courts and if a computer program about parenting can be useful to parents.
- **PROCEDURES:** You will be asked to complete personal questionnaires and have a videotaped discussion with your teenager relating to drug use behaviors. You will then be randomly chosen to either: 1) watch a computer video on parenting and receive daily text messages for up to 6 months on parenting; or 2) receive handouts on parenting and teen marijuana use.
- Your teenager will be asked to complete an interview, questionnaires about his/her marijuana and alcohol use and some other topics related to marijuana use, provide a urine drug screen, have a videotaped discussion with you. He/she will then be randomly chosen to either: 1) watch a computer video on cutting down or quitting marijuana use or 2) receive handouts on marijuana use.
- **TIME INVOLVED:** This study starts today and involves two more sessions, in one week and then 3 and 6 months from now. Each session will take up to 2 hours of your time.
- **COMPENSATION:** You will receive \$50 for each session for your time. If you respond to our request to update your contact information in a few months, you will receive an additional \$5 (total amount possible - \$155).
- **RISKS:** You may feel uncomfortable about the sensitive topics discussed or being videotaped, and there is a chance of loss of privacy and confidentiality affecting your teenagers' reputation and employment
- **BENEFITS:** You may learn some parenting strategies and teens may learn about ways to cut down or stop smoking marijuana.
- **ALTERNATIVES TO PARTICIPATION:** The alternative is not to participate.

1. **Researcher:** This research is being conducted by Anthony Spirito, Ph.D. He may be contacted at [anthony\\_spirito@brown.edu](mailto:anthony_spirito@brown.edu) or 401-444-1929. This research is sponsored by the National Institutes of Health.

2. **What is the study about?**

You are being asked to participate in this study because your teenager is involved with the courts. The study starts today and involves two more sessions 3 and 6 months from now. We are trying to figure out new ways to help court-involved teenagers who have been using marijuana. We are studying if a brief computer program about ways to cut down or quit smoking marijuana can be helpful to teens. We are also giving extra support to parents/guardians by having them watch a computer program about parenting. We will use the results of this study to develop new ways to help teens and support parents of teens who are involved with the courts. Therefore, we are interested in obtaining both you and your teen's opinions on the research program.



### **3. What will I be asked to do?**

Today, your teenager will 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 as well as communication with you about marijuana use, and your rules at home, such as curfews. Your teen will also be asked to provide a urine drug screen. If your teen is intoxicated, we will reschedule their interview for another day. Urine drug screens will be given at the start of each assessment to indicate recent use and corroborate self-report.

In separate rooms, you and your teen will complete questionnaires about your family, your communication with each other, and household rules. You will not be able to see each other's responses to these questionnaires. You and your teen's interview and questionnaires should take about 1 hour to complete.

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, chores, going out with friends, as well as discussions about your beliefs regarding behaviors such as drinking and drug use. This discussion will be videotaped. The video tapes will be erased at the end of the project.

After you complete your videotaped meeting, you will be randomly assigned into one of two study groups. Randomly means that you are put into a group by chance. It is like flipping a coin. In one group, you will receive some handouts about marijuana use and teenagers.

In the other group, either today, if you would like, or in about a week, you will come back to watch the computer program about different parenting skills and will learn how to use a computerized program called Parenting Wisely that will help you practice skills. Your teen will watch a computer program about ways to cut down or stop using marijuana. You will also receive a daily text based message providing advice and support parenting teens, for up to six months. This will be done through an app that we download on your phone. After the study is over, the app will be removed by study staff or you can delete it yourself. Most phone plans do not incur a charge to receive the study text messages, but you should check if there are any charges before agreeing to participate in this study.

Study staff will collect court-related information relevant to your teen and their involvement in 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; data from the participant's initial mental health screening at the Rhode Island Family Court, if applicable; and previous mental health treatment and referrals for mental health treatment.

Three and six months from now, regardless of which study group you are in, you and 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. You will also be asked your opinions about the research program. This visit should take 1 ½ to 2 hours.

We will make every effort to contact you and remind you of these study visits. Therefore, as part of your participation in this project, we will ask your permission to contact two people who know you well enough to know how to reach you in the case that there is a change to your contact information. We may use telephone calls and letters to reach out to your family or friends. We





# BROWN

will not inform any other individual about the nature of this research study or speak with them about any of the confidential material you have given us as part of this study.

## 4. Will I be paid?

You and your teen will each receive \$50 for answering questionnaires today and \$50 when you come back in 3 and 6 months. If you and your teen complete all three of these interviews, you will each receive \$150 in total. If you respond to our request to update your contact information in a few months, you will receive an additional \$5.

## 5. What are the risks?

The questionnaires that you and your teenager will answer are commonly used in research and clinical practice. It is possible that you and your teenager may become upset or experience emotional distress when answering questions about your teen's substance use, and when being videotaped discussing house rules related to substance use. 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 Dr. Spirito, a licensed clinical psychologist, at any time if you become upset or experience emotional distress. You and your teenager will be asked sensitive information about a number of behaviors including alcohol and drug 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 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 8 below.

Some of the information collected in this study will be sent outside of Brown. A vendor named Silent Disclosure will be responsible for sending parents text messages, 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 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 one way 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. These messages will be sent using an app we download on your phone.

## 6. What are the benefits?

This study may not benefit you or your teen personally. However, by answering these questions and taking part in the family interview, teenagers and their parents may have the opportunity to learn more about alcohol use, family interactions, and ways to improve communication. Also, parents will have the opportunity to learn new parenting skills and get additional support. We hope that this study will help us to design a parenting program to help other families have better outcomes.

## 7. Are there any alternatives to this study?

The alternative is not to participate.

## **8. How will my information be protected?**

All of your and your teenager's records from this study will be treated as private records. Your name and your teenager's name will not be on the questionnaires. During audio or video assessments, you 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 and laptop computer data will be stored on a secure server or a password protected, encrypted external hard drive stored in a locked cabinet. Only researchers working on this study will have access to the information provided by you.

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, Youth and Families (DCYF). 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.

Participation in research may cause a loss of privacy. In this study, you and your child will be asked about drug use and other sensitive activities. We will do everything we can to keep others from learning about you and your child's participation in the research. To help keep your 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 a member of your family from voluntarily releasing information about the study or your involvement in this research. This means that you and your family must also actively protect your privacy.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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 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.

**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 without penalty. 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](mailto: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 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.

---

Participant's Signature and Date

/

PRINTED NAME

---

Research Staff Signature and Date

/

PRINTED NAME