

Consent Form for Research Participation

For Caregivers and Parents/Legal Guardians of Minor Participants

Sponsor / Study Title: RTI International / “Evaluating an ACE-Targeting Advocate Model of a Substance Use Prevention Program: A Hybrid Type 1 Effectiveness-Implementation Trial”

Protocol Number: [REDACTED]

Principal Investigator: [REDACTED]

Telephone: [REDACTED]

Address: [REDACTED]

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Your participation is voluntary.

Key Information for You to Consider

- **Voluntary Consent:** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose:** We are asking you to take part in a research study about a prevention-based approach designed to reduce the harms of Adverse Childhood Experiences (ACEs) and prevent future ACEs, substance use, and overdose.
- **Risks:** There are minimal risks involved in taking part in the study activities. You may feel uncomfortable answering questions about ACEs or substance use issues. You can skip any survey questions that you do not feel comfortable answering. You do not need to put your name on the survey. There is a small chance that someone could see survey answers, but nobody’s answers are stored with their names. There may be other risks that are unknown.
- **Benefits:** There are multiple direct and indirect benefits associated with participating in the study. The Strengthening Families Program is an evidence-based program that can increase family functioning, increase awareness of ACEs, and decrease substance use. Throughout the study, you may also experience improved access to community resources that may help with ACEs or substance use issues. Finally, your participation in this study may also help to benefit other communities and families experiencing disproportionate levels of ACEs or substance use issues.
- **Alternatives:** Participation is voluntary and the only alternative is to not participate.

Who is doing the study?

We are from RTI International (RTI), the New Jersey Prevention Network (NJPN), and RWJBarnabas Health Institute for Prevention and Recovery (RWJBH IFPR). NJPN, RWJBH IFPR, and RTI have years of experience developing prevention, treatment, and recovery support services throughout New Jersey and doing research studies.

What would I be asked to do?

If you agree to take part, we will ask you to:

- Fill out 3 confidential online surveys over the course of 9 months that will take about 15-20 minutes to finish. You can choose to skip any questions you do not want to answer.

You can also stop taking the survey at any time. The survey includes questions about your views and experiences on parenting, family functioning, and substance use.

- Fill out 2 ACEs and Social Needs Screeners over the course of 9 months that will take about 15-20 minutes to finish each. You can choose to skip any questions you don't want to answer. You can also stop taking the screener at any time. The screener includes questions about stressful life events and social needs that can affect your family's health and wellbeing. We would like to ask you these questions so that we can help your family be as healthy as possible.
- Complete confidential online surveys after each Strengthening Families Program session. These surveys will take about 5 to 10 minutes and ask for your feedback on the session.
- Finally, you will be given the option of deciding whether you would like to have your oldest child between the ages of 12 and 17 complete only the 3 confidential online surveys over the course of 9 months. If you give your permission, your child will be given their own assent form that contains important information about this study and what to expect if they decide to participate.

About 360 families will participate in this study.

Compensation

You can receive e-gift cards for completing study activities, in addition to the gift cards you will receive for weekly attendance at Strengthening Families Program sessions. You will get e-gift cards worth \$50.00 for completing the initial survey and screener and \$50.00 for completing a second survey and screener 6 months after completing the Strengthening Families Program.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

If you have any questions regarding your compensation for participation, please contact the study staff.

Will you share my information with anyone?

We will not share your name, email, your data, or any other identifying information with anyone or any organization outside the RTI, NJPN, and RWJBH IFPR study team. Your name will not be listed in any reports we write. Your identifiable private information will not be used or distributed to others for future research.

To help keep information about you confidential, we have obtained a certificate of confidentiality (CC) from the Centers for Disease Control and Prevention (CDC). This CC adds special protection for the research information about you. The CC will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. We may release identifying information in some circumstances, however. For example, we may disclose medical information in cases of medical necessity, or take steps (including notifying authorities) to protect you or someone else from serious harm, including child abuse or neglect.

Are there any costs involved?

There are no costs to you to take part in this study. Depending on your data plan, message and data rates may apply if you are not on Wi-Fi while completing the surveys.

Do I have to take part?

No. It is your choice. These activities are voluntary. There is no penalty if you choose not to take part. You will not lose benefits or access to any services you receive now or in the future.

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Who to contact about this study

Please contact the Co-Principal Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By mail:

[REDACTED]

- or call toll free:

- or by email:

[REDACTED]

Please reference the following number when contacting the Study Subject Adviser:

[REDACTED]

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.

How do I show I want to take part?

If you want to take part in the study, please mark the YES box below. If you do not want to take part, please mark the NO box.

Please select your response.

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact.

☐ YES — I agree to participate in the research study.

☐ NO — I do not agree to participate in the research study.

Enter today's date (mm/dd/yyyy):

Participant's first name:

Participant's last name:

When is your birthday? (mm/dd/yyyy)

Being able to access your email is going to be very important for receiving the survey and your gift cards. Please type an email address for an email account that you check frequently.

Email address:

Please re-enter your email address, this helps to ensure that we are sending your surveys and gift card to a valid and accurate email address:

Mobile phone number (Please list area code and number; *we highly encourage you to provide a mobile phone number so that you can access the survey by phone, but if you do not have a mobile phone number, please put 999-999-9999*):

Please re-enter your mobile phone (area code and number) again:

Parental/Legal Guardian's Permission for Child's Participation in Research

I give permission for my oldest child (between the ages of 12 and 17) to participate in the research study described above and will receive a copy of this form.

Child's first name:

Please select your response.

- ☐ YES — I agree to allow my child to participate in the research study.
- ☐ NO — I do not agree to allow my child to in the research study.

Enter today's date (mm/dd/yyyy):

WITNESS ATTESTATION (IF APPLICABLE)

I attest that:

- The information in the consent form and any other written information was accurately explained to and apparently understood by the participant; and
- Informed consent was freely given by the participant.

Please select your response.

- ☐ YES — I agree to participate in the research study.
- ☐ NO — I do not agree to participate in the research study.

Assent to Participate in Research

For Minor Subjects between 12 and Age of Majority (AOM)

This is an assent form for research participation. It contains important information about this study and what to expect if you decide to participate. Your participation is voluntary. Please read the content below and press "submit" if you agree to participate in this study.

Thank you!

Sponsor / Study Title: RTI International / "Evaluating an ACE-Targeting Advocate Model of a Substance Use Prevention Program: A Hybrid Type 1 Effectiveness-Implementation Trial"

Protocol Number:

Principal Investigators:

Telephone:

Address:

What is this study about?

This is a research study about a prevention-based approach designed to reduce the harms of Adverse Childhood Experiences (ACEs) and prevent future ACEs, substance use, and overdose.

What will I need to do if I am in this study?

If you agree to take part, we will ask you to:

- Fill out 3 confidential online surveys over the course of 9 months that will each take about 15-20 minutes to finish. You can choose to skip any questions you don't want to answer. You can also stop taking the survey at any time. The survey includes questions about your views and experiences on your family, substance use, and peer behaviors.

You will get a e-gift card worth \$50.00 for completing the final survey and screener 6 months after completing the Strengthening Families Program.

What bad things might happen to me if I am in the study?

To the best of our knowledge, the things you would be doing in this study have no more risk of harm than the risks of everyday life. You may feel uncomfortable answering questions about ACEs or substance use issues. You can skip any survey questions that you do not feel comfortable answering. You do not need to put your name on the survey. There is a small chance that someone could see survey answers, but nobody's answers are stored with their names.

What good things might happen to me if I am in the study?

There are multiple direct and indirect benefits associated with your participation in the study. Strengthening Families Program is an evidence-based program that can increase family functioning, increase awareness of ACEs, and decrease substance use. Throughout the study, you may also experience improved access to resources in your community that may help with ACEs or substance use issues. Finally, your participation in this study also may help to benefit other communities and families experiencing disproportionate levels of ACEs or substance use issues.

What will you do with information about me?

We will be very careful to keep your answers confidential. We will not share your name, email, your data, or any other identifying information with anyone or any organization outside the study team. Your name will not be listed in any reports we write.

Are there any costs involved?

There are no costs to you to take part in this study. Depending on your data plan, message and data rates may apply if you are not on Wi-Fi while completing the surveys.

Do I have to take part?

No. It is your choice. These activities are voluntary. There is no penalty if you choose not to take part. You and your family will not lose benefits or access to any services you receive now or in the future.

What if I have questions?

You can contact the investigators listed on the first page of this document if you have questions about the study.

Agreeing to be in the research:

- You will receive the first of three confidential online surveys via text message or email. By deciding to take the first survey, you agree to participate in the research study described above. You will receive a copy of this form for your records.

Please select your response.

- ☐ YES — I would like to be in this study.
- ☐ NO — I would not like to be in this study.

Please enter your initials: _____