

National Child Traumatic Stress Initiative (NCTSI) Evaluation

SAMPLE INFORMED CONSENT—CAREGIVER

(Suggested Content and Wording)

Purpose

The Substance Abuse and Mental Health Services Administration (SAMHSA) in the United States Department of Health and Human Services is studying the National Child Traumatic Stress Network funded by the National Child Traumatic Stress Initiative (NCTSI). The NCTSN program is funded to improve access to quality care for children who have experienced trauma and their families. The ***(NCTSN Center Program Name)*** where your child has received services is a part of this project. This project will be used to help make services for traumatized children and their families better.

Description of Participation

As a part of this project, you will be interviewed initially at intake, every 3 months until treatment ends, and then at the end of treatment with ***(NCTSN center program name)***. We will talk with you at the clinic, home, or at any other place that is best for you. In the interviews, we will be asking you about your child's symptoms and behaviors, and about the services your child has received. This will take about 2 hours.

If your child reaches age 11 at any time during this project, we will ask your child if we can interview him or her. At that time, we will ask for your permission to talk to your child. We will also describe the interview process to your child.

Risks and Benefits

There are no direct benefits to you being a part of this project. Your child may benefit from the treatment he/she receives. You may also learn new things about your child. As a result of this project, services for traumatized children with mental health needs may get better. You may feel uncomfortable when talking about personal matters. We have taken steps to protect your privacy and information regarding this will be provided later in the consent process.

Compensation

If you agree to participate in this project, you will receive a thank you gift. You will receive \$XX for your first interview and \$XX for each follow-up interviews.

Contact Information

If you have any questions about this evaluation project, you can call ***(evaluator)*** to have your questions answered. You can call him/her collect at (555) 555-5555. To contact the Institutional Review Board that reviewed this project, call (555) 555-5555.

Protection of Information

Special precautions will be taken to protect your child's and your privacy. No agency that you are involved with, including schools, will have access to the information you provide. All forms in the project will be coded so that they cannot be associated with individual names. In reports, the information summarized will never mention individual names.

Rights Regarding Decision to Participate

I understand that if I agree to take part in this project, I can change my mind and quit at any time. If I change my mind and quit, any information I gave to the project will be destroyed, if this is what I want. If I decide not to be in this project, it will not affect services for my child and family. It also will not affect services that we might want in the future.

Voluntary Consent

I have read this form or, it has been read to me, and I understand what it says. My questions have been answered. A copy of this form will be given to me. By signing my name below, I freely agree:

▪ to be interviewed every 3 months, until treatment ends _____
Caregiver/Guardian (Type or Print Full Name): _____

Signature of Caregiver/Guardian:

_____ Date: ___/___/___

Name of Child/Youth (Print) _____

Date: ___/___/___

Key Components of a Consent Form

Elements to Include:

Purpose of the Study

- Funding source
- Local NCTSN center/program name
- Description of why the study will be conducted

Description of Participation

- Participant responsibilities
- Description of data collection methods: interviews--frequency, duration; record review; observation, etc.
- Description of child/youth involvement
- Other guidelines (e.g., possible data sources, age, changes in participation over time, etc.)

Risks and Benefits

- Potential risk factors associated with participation
- Potential benefits that may be gained through participation

Compensation for Participation

- Type and amount of compensation participant will receive for participation
- Process or schedule for payment

Contact Information

- Contact information for someone working on the study who will be available to answer participant questions

Protection of Information

- Protocol for maintaining participant privacy
- Description and purpose of the Federal Certificate of Confidentiality
- Mandated reporting requirements

Rights Regarding Decision to Participate

- Statement of participant rights to terminate participation at will
- Statement that the termination of participation will not lead to adverse consequences

Voluntary Consent

- Statement of participant understanding of the consent form
- Statement that participant has had all of his or her questions answered
- Permission to be interviewed
- Permission to access service provider records for 12 months previous to service and 24 months after the first service
- Signature line for participant to sign, thus granting consent to participate
- Date