

ADOLESCENT ASSENT FOR PARTICIPATION IN A RESEARCH PROJECT**YALE UNIVERSITY SCHOOL OF MEDICINE**

Study Title: Cognitive-Behavioral Therapy for Teens Who Experienced Weight-related Bullying

Principal Investigator (the person who is responsible for this research): Janet Lydecker, Ph.D.

Phone Number: 203-737-4299

Funding: Yale Center for Clinical Investigations

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this project is to look at the effects of a new treatment for adolescents who have been bullied because of weight.
- Study procedures will include: an interview with a research clinician at the beginning and end of treatment that will ask questions about your health, eating behaviors, and any psychological or physical problems. You will complete interviews and also fill out surveys. There will also be weekly treatment for three months. There will also be monthly check-ins that your parent will attend when you will both fill out surveys.
- **13** visits are required: 1 before treatment, and 12 treatment sessions (monthly check-ins and the end-of-treatment visit will occur on the same days as treatment sessions). A parent attends the visit before treatment, the first session, monthly check-ins, and the end of treatment visit.
- These visits will take up to **15** hours total, spread over at least 3 months.
- There are no physical risks associated with this project. The treatment in this study (“talk therapy”) does not involve many risks, but you may feel uncomfortable when thinking about or discussing bullying, eating or weight. There is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. There is a chance that your mood or eating may not get better or may get worse during the study. You will be withdrawn from the study if the clinical condition becomes significantly worse.
- The study may have not directly benefit you. The talk therapy we will be using is known to be helpful to some teens who have had other kinds of trauma, but we do not know if it will help teens who have been bullied. We believe that some of the knowledge we learn from this study will be used to make treatments for weight-related bullying for adolescents better.
- There are other choices available to you outside of this research. There are treatments for weight loss and other treatments (talk therapies) for eating disorders. If you choose not to participate in this project, we can give you referrals for alternative treatments.
- Taking part in this project is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, your relationships with your own doctors will not change and you will not give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask your clinician questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will sign this form.

Why is this study being offered to me?

We are asking you to take part in a research project because you are between 11 and 17 years old, and have experienced weight-related bullying that is currently upsetting you. We are looking for 30 teens to participate in this study.

Who is paying for the study?

The Yale Center for Clinical Investigations, which is funded by the National Institutes of Health and Yale University School of Medicine, is providing funding for this project.

Who is providing other support for the study?

No one else is providing support for the project.

What is the study about?

This study is looking at how well a new treatment works. The treatment is cognitive-behavioral therapy (sometimes known as talk therapy). Talk therapy is known to work for teens with other forms of trauma, but how well it works with teens who have been bullied because of weight is not known.

Where will this study take place?

We will be meeting with you by calling you using a video (or audio) application.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen:

1. Intake Appointment: Your first appointment will be with a research clinician. During this visit, we will ask questions about your health, your eating behaviors, any alcohol or drug use, and any other psychological and physical problems that you may have now or may have had in the past. Because you will be meeting with us over video/phone, we will also pre-problem-solve what to do if safety concerns come up at some point during this treatment. You, your clinician, and your parent will come up with a plan together. At this first appointment, we will also ask you what your weight and height are. After you talk with us, we will also ask you to fill out surveys. Your parent will also answer some survey questions. This visit will take approximately 2 hours.

2. Treatment: If you are a good fit for this program and decide to participate, you will receive talk therapy for 3 months. You will talk with a clinician weekly and your parent will join you for check-ins once a month. This therapy will focus on learning new coping skills, learning specific behaviors that help you take care of yourself, changing some things about how you think about the bullying and your weight and shape. We will keep track of your weight during these sessions. Each session will take approximately 1 hour. We will also ask you questions about what you liked or did not like about treatment so far, and whether you think it is or is not helping you.

3. Monthly Check-ins: While you are in treatment, we will check on how things are going once a month. We will ask you (and your parent) to fill out surveys. These check-ins will happen during your scheduled treatment session.

4. End of Treatment Interview: At the end of treatment, you will meet with a research clinician again who will ask questions about your health, your eating behaviors, and what you thought about treatment. We will also ask you to tell us your weight and height and ask you and your parent to answer some survey questions. This visit will take approximately 2 hours.

	Intake	Month 1	Month 2	Post
ADOLESCENT				
Interviews	*			*
Surveys	*	*	*	*
Height and weight	*	*	*	*
Treatment credibility	*			
Ratings of session content		*	*	*
PARENT				
Surveys	*	*	*	*
Weight (height: at intake only)	*	*	*	*
Treatment credibility	*			
Ratings of session content		*	*	*

What are the risks and discomforts of participating?

There are no physical risks associated with this study. The treatment in this study (“talk therapy”) does not involve many risks, but you may feel uncomfortable when thinking about or discussing bullying, eating and weight.

There is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

There is a chance that your mood or eating may not get better or may get worse during the study. You will be withdrawn from the study if your clinical condition becomes significantly worse.

How will I know about new risks or important information about the study?

We will tell you and your parent if we learn any new information that could change your mind about taking part in this study.

What if I turn 18 while I’m in the study?

If you turn 18 while you are in the study, we will have you sign an adult consent form. Your parent will continue to participate in study visits and complete surveys as described in this consent form.

How will this study benefit me?

You might not have any direct benefit from this study. The talk therapy is known to be helpful to some teens who have other kinds of trauma, but we do not know if it will help teens who have been bullied. We cannot determine ahead of time whether you will personally benefit or how much you will benefit.

The evaluations and treatment will be provided by experienced clinicians free of charge. The interviews and surveys may help you to better understand your problems. We will discuss findings with you.

How can the study possibly benefit other people?

We believe that some of the knowledge from this study will be used to improve treatments for adolescents and to increase our understanding of weight-related bullying.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include your time attending to the study visits. If there are any findings about medical or psychological conditions, we may recommend that you see your doctor or therapist. If you choose to do this, your or your family's health insurance must pay for services, supplies, procedures, and care that are not part of this study.

Will I be paid for participation?

You will be paid for taking part in this study. You will be paid for each monthly check-in and for the interview at the end of treatment. You will get \$20 at each monthly check-in and \$40 for the interview at the end of treatment. The treatment and evaluations will be free of charge.

What are my choices if I decide not to take part in this study?

Instead of doing this treatment study, you have some other choices.

You could:

- Get treatment without being in a study. You could do a treatment for weight loss or another talk therapy that focuses on eating disorders. These treatments do not generally talk about bullying. If you choose not to participate in this study, we can give you referrals for alternative treatments.
- Take part in another study.

How will you keep my data safe and private?

Any identifiable information that we obtain about you during this study will stay confidential and will be shared only if you agree to it. There are also situations when US or state law requires us to release your information (such as your name), for example, if you tell us that you are planning to hurt yourself or someone else, or if you know of a child or an elderly person being abused. When we publish the results of the research or discuss them at conferences, no information will be included that would reveal your identity unless you allow us to do so.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless your parent has consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if your parent has consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, your parent must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, elder abuse, or harm to self or others.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the research team will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, address, telephone number, email address, and date of birth. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. All records will be kept in locked cabinets separate from any identifying information, and all computer records will be password-protected. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 7 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

Recordings

If you are willing, the interviews and treatment sessions will be recorded. This is not required for you to participate. We will not use your name during the recording. If you are willing and agree to the recording, we will ask you to sign a separate section below. If you do agree to recording, all audio records will be erased after the completion of this study (five years) or at any time at your request.

What Information Will You Collect About Me?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The information about your health that will be collected in this study includes:

- Research study records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
 - Diaries and questionnaires
 - The diagnosis and treatment of a mental health condition
 - Use of illegal drugs

Your parent(s) will be told that they cannot have access to any of the research information, including surveys, interviews, and treatment information. They will be informed that if you report any information to us about abuse or plans to hurt yourself or someone else, we will be required to report this information to the appropriate authorities. If you tell us you are a danger to yourself or others, we may need to tell your parent(s) to make sure you are safe.

Authorized representatives from the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), the Yale Center for Clinical Investigations, and the National Institutes of Health, may need to review records of individual subjects. As a result, they may see your name; but they are also required to protect your privacy and not reveal your identity.

How will you use and share my information?

We will use your information to do the study described in this form.

In addition, information about you and your health which might identify you may be used by or given to:

- The US Department of Health and Human Services (DHHS) agencies
- The committees at Yale, and their representatives, who review, approve, and monitor this research study. These individuals are required to keep all information confidential.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator (Dr. Janet Lydecker)
- Members of the Research Team
- Study Safety Monitor and others authorized to monitor the conduct of the Study: Dr. Mona Sharifi

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes.

What if I change my mind?

If you decide to take part in this study, and then change your mind, you can stop and withdraw from this study at any time. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled (like your health care). It will not harm your relationship with your own doctors or with the Yale School of Medicine.

To stop your participation in the study, you can write to the principal investigator at any time: Dr. Janet Lydecker, janet.lydecker@yale.edu, 300 George Street at Yale University School of Medicine, New Haven, CT 06520, and tell her that you no longer want to take part. This will cancel any future appointments. Even if you stop participating in the study, the researchers will still be able to use the information that has already been collected about you. That information could also be given to others until the end of the research study, to make sure that the study produces valid results.

At your request, we would refer you to a clinic or doctor who can offer treatment. Not participating or withdrawing later will not harm your relationship with your own doctors, or with this institution.

The researchers may withdraw you from participating in the research if necessary. For example, if you were to start other treatments for trauma, if your symptoms get worse, or if you are not coming to study appointments.

What will happen with my data if I stop participating?

If you are no longer participating, information that has already been collected may still be used and given to others. Your identity will not be connected to the data.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203-737-4299**.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator *Janet Lydecker, Ph.D. (203-737-4299)*. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688. If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

Authorization and Permission

My signature below means that I have read (or someone read to me) this form and I decided to participate in the project that was described.

We will give you a copy of this form.

Name of Participant: _____

Signature: _____

Date: _____

Signature of Person Obtaining Assent

Date

Consent to Record Interviews/Sessions:

My signature below indicates that you agree to allow video and/or audio recording.

☐ Audio only

☐ Audio and video

☐ Neither audio nor video

Signature: _____

Date: _____

Signature of Person Obtaining Assent

Date

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Cognitive-Behavioral Therapy for Teens Who Experienced Weight-related Bullying

Principal Investigator (the person who is responsible for this research): Janet Lydecker, Ph.D.

Phone Number: 203-737-4299

Funding: Yale Center for Clinical Investigations

Research Study Summary:

- We are asking you to join a research study and allow your child to join a research study.
- The purpose of this research study is to look at the effects of a new treatment for adolescents who have been bullied because of weight.
- Study procedures will include: an interview with a research clinician at the beginning and end of treatment that will ask questions about your child's health, eating behaviors, and any psychological or physical problems. You and your child will both fill out surveys. There will be weekly treatment for your child for three months. There will be monthly check-ins with you and your child when you will both fill out surveys.
- **13** visits are required for your child: 1 before treatment, and 12 treatment sessions (monthly check-ins and the end-of-treatment visit will occur on the same days as treatment sessions). A parent attends **5** visits: before treatment, first session, monthly check-ins, and end of treatment.
- These visits will take up to **15** hours total, spread over at least 3 months.
- There are no physical risks associated with this study. The treatment in this study ("talk therapy") does not involve many risks, but you or your child may feel uncomfortable when thinking about or discussing eating and weight. There is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. There is a chance that your child's mood or eating may not improve or may worsen during the study. Your child will be withdrawn from the study if the clinical condition becomes significantly worse.
- The study may have no direct benefit to you or your child from your participation or your child's participation in this study. The cognitive-behavioral treatment is known to be helpful to youth with other forms of trauma, but we do not know if it will be help teens who have experienced bullying related to weight. We anticipate that some of the knowledge from this study will be used to improve treatments for adolescents and to increase our understanding of weight-related bullying.
- There are other choices available to you outside of this research. Lifestyle treatments to prevent gaining more weight are available without enrolling in the study. These types of programs do not generally talk about bullying. Cognitive behavioral therapy for eating disorders and interpersonal psychotherapy are "talk therapy" that may help treat any eating disorder behaviors you currently have, but again do not generally talk about bullying. If you choose not to participate in this study, we can give you referrals for alternative treatments.

- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you and your child to take part in a research study because your child has experienced weight-related bullying, is currently upset about the bullying, and is between 11 and 17 years old. We are looking for 30 teens to participate in this study.

Who is paying for the study?

The Yale Center for Clinical Investigations, which is funded by the National Institutes of Health and Yale University School of Medicine, is providing funding for this study.

Who is providing other support for the study?

No one else is providing support for the study.

What is the study about?

The purpose of this study is to look at how well a new treatment works on weight-related bullying. The treatment is cognitive-behavioral therapy (sometimes known as talk therapy). Cognitive-behavioral therapy is known to work for youth with other forms of trauma, but how well it works with teens who have been bullied because of weight is not known.

Where will this study take place?

This study will be conducted using “telehealth,” meaning that your clinician will call you using a video (or audio) application.

What are you asking me to do and how long will it take?

If you agree to take part in this study and allow your child to take part, this is what will happen:

1. **Intake Appointment:** For the first appointment, you and your child will meet with a research clinician. During this visit, we will ask questions about your child’s health, eating behaviors, any alcohol or drug use, and any other psychological and physical problems that your child may have now or may have had in the past. Because this treatment is taking place remotely and you might not live in the New Haven area, we will talk about a safety plan to address suicidal thoughts in case they come up at some time during treatment. At this first appointment, we will also ask you to tell us your weight and height and your child’s weight and height from a recent measurement. We will also ask you and your child to do surveys. This visit will take approximately 2 hours.

2. **Treatment:** If your child is eligible for treatment and decides to participate, they will receive cognitive-behavioral therapy for 3 months. Each session will take approximately 1 hour. Your

child will meet with a clinician weekly during this treatment and you will join them for treatment once a month. This therapy will focus on learning new coping skills, learning specific behaviors that help you take care of yourself, and changing some things about how your child thinks about the bullying they experienced and about weight/shape. We will also ask your child to tell us their weight during these sessions and ask for feedback about what they liked or did not like about treatment so far and what they think is helpful or not helpful.

3. Monthly Check-ins: While your child is in treatment, we will check on how things are going once a month. We will ask you and your child to fill out surveys. These check-ins will happen as part of the scheduled treatment sessions.

4. End of Treatment Interview: At the end of treatment, you and your child will meet with a research clinician again who will ask questions about your child's health and eating behaviors. We will also ask you and your child to tell us your recently-measured weight and height and ask you and your child to answer some questions on surveys. This visit will take approximately 2 hours.

	Intake	Month 1	Month 2	Post
ADOLESCENT				
Interviews	*			*
Surveys	*	*	*	*
Height and weight	*	*	*	*
Treatment credibility	*			
Ratings of session content		*	*	*
PARENT				
Surveys	*	*	*	*
Weight (height: at intake only)	*	*	*	*
Treatment credibility	*			
Ratings of session content		*	*	*

What are the risks and discomforts of participating?

There are no physical risks associated with this study. The treatment in this study ("talk therapy") does not involve many risks, but you or your child may feel uncomfortable when thinking about or discussing bullying, eating and weight.

There is the possible risk of loss of confidentiality. Every effort will be made to keep your and your child's information confidential; however, this cannot be guaranteed.

There is a chance that your child's mood or eating may not improve or may worsen during the study. Your child will be withdrawn from the study if their clinical condition becomes significantly worse.

How will I know about new risks or important information about the study?

We will tell you and your child if we learn any new information that could change your mind about taking part in this study.

What if my child turns 18 while in the study?

If your child turns 18 while in the study, we will have them sign an adult consent form. You will continue to participate in study visits and complete surveys as described in this consent form.

How will this study benefit me/my child?

There may be no direct benefit to you or your child from your participation in this study. The cognitive-behavioral treatment is known to be helpful to some youth with other forms of trauma, but we do not know if it will help teens who have been bullied because of weight. We cannot determine ahead of time whether your child will personally benefit or how much your child will benefit.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of weight-related bullying, as well as how to treat weight-related bullying for teens. This study may lead to new treatments.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include your time attending to the study visits. If there are any findings about medical or psychological conditions, we may recommend that your child see a doctor or therapist. If you choose to do this, you or your health insurance must pay for services, supplies, procedures, and care that are not part of this study.

Will I be paid for participation?

You and your child will be paid for taking part in this study. You will be paid for each monthly check-in and for the interview at the end of treatment. You will get \$20 at each monthly check-in and \$20 for the interview at the end of treatment. Your child will be paid separately--\$20 at each monthly check-in and \$40 for the end of treatment interview--for participation. The treatment and evaluations will be free of charge.

You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide that my child will not to take part in this study?

Instead of participating in this study, you have some other choices.

You could:

- Get treatment for your child without being in a study. There are certain available treatments for eating disorders, such as cognitive-behavioral therapy and interpersonal psychotherapy. These treatments do not generally talk about bullying. If you choose not to participate in this study, we can give you referrals for alternative treatments for your child.
- Take part in another study.

How will you keep my and my child's data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, if you or your child tell us about plans to hurt yourself or someone else, or if you or your child know of a child or an elderly person being abused.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

This study is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you or your child in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your child, or your child's involvement in this research. If you want your child's research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, elder abuse, or harm to self or others.

We understand that information about your child obtained in connection with your child's health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the research team will get information that identifies you and your personal health information. This may include information that might directly identify your child, such as your name, address, telephone number, email address, and date of birth. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your child's identifying information with a code that does not directly identify you. The principal

investigator will keep a link that identifies you and your child to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify will remain confidential. All records will be kept in locked cabinets separate from any identifying information, and all computer records will be password-protected. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 7 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

If you sign this form, you are giving permission for the use and/or disclosure of your health information for this research study. You do not have to give this permission. However, if you do not give permission, you will not be able to take part in the study.

This authorization to use and disclose your and your child's health information collected during your participation in this study will never expire.

You do not give up any of your or your child's legal rights by signing this form.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

Recordings

If you are willing, the interviews and treatment sessions will be recorded. This is not required for you to participate. The purpose is for us to see the clinician providing the treatment. You will not have to watch or listen to your recordings. We will not use your or your child's name during the recording.

If you are willing and agree to the recording, we will ask you to sign a separate section below. If you do agree to recording, all audio records will be erased after the completion of this study or at any time at your request.

What Information Will You Collect About Me and My Child in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical records of only those services provided in connection with this study.
- Records about phone calls made as part of this research

- Records about your study visits
- Information obtained during this research regarding
 - Diaries and questionnaires
 - The diagnosis and treatment of a mental health condition
 - Use of illegal drugs or the study of illegal behavior

You cannot have access to any of the research information, including surveys, interviews, and treatment information that your child provides. If your child reports any information to us about abuse or plans to hurt himself or herself or someone else, we will be required to report this information to the appropriate authorities. If your child tells us they are a danger to themselves or others, we may need to tell you to make sure your child is safe.

How will you use and share my and my child's information?

We will use your and your child's information to conduct the study described in this consent form.

We may share your information with:

- The US Department of Health and Human Services (DHHS) agencies.
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator (Dr. Janet Lydecker)
- Members of the Research Team
- Study Safety Monitor and others authorized to monitor the conduct of the Study (Dr. Mona Sharifi)

We will do our best to make sure your and your child's information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your and your child's information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes.

What if I change my mind?

The authorization to use and disclose your and your child's health information collected during your participation in this study will never expire. However, you may withdraw or take away

your permission at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Janet Lydecker, janet.lydecker@yale.edu, 300 George Street at Yale University School of Medicine, New Haven, CT 06520.

If you withdraw your permission, you and your child will not be able to stay in this study but the care you get from your doctor and your child's doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to allow your child to take part, or you can choose not to allow your child to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your or your child's medical care or give up any legal rights or benefits.

At your request, we would refer you to a clinic or doctor who can offer treatment. Not participating or withdrawing later will not harm your relationship with your own doctors, your child's doctors, or with this institution.

To withdraw from the study, you can write to the principal investigator at any time and tell her that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. For example, if your child were to start other treatments for trauma, if your child's symptoms worsen, or if you or your child are not attending study appointments in a way that makes it impossible for us to provide the treatment that is part of this study.

What will happen with my data if my child stops participating?

If you and your child are no longer participating, information that has already been collected may still be used and given to others. Your and your child's identities will not be attached to the data.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203-737-4299**.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study and allow your child to be in this study.

We will give you a copy of this form.

Child's Name

Parent Printed Name

Parent Signature

Date

Person Obtaining Consent Printed
Name

Person Obtaining Consent Signature

Date

Consent to Record Interviews/Sessions:

Your signature below indicates that you agree to allow video and/or audio recording for you and your child.

[] Audio only

[] Audio and video

[] Neither audio nor video

Signature: _____

Date: _____

Signature of Person Obtaining Consent

Date