Youth Assent Form

(For ages 12 - 18)

Approval Date: July 31, 2016

Courage to Act with Pain: Teens Identifying Values, Acceptance, & Treatment Effects (CAPTIVATE)

1. What will happen to me in this study?

The CAPTIVATE group will meet one day each week for 10 weeks to talk about thoughts, feelings, and behavior related to discomfort and being a teenager. This study is not an experiment but does involve learning ways to manage thoughts, feelings, activities, and comfort by working with other teens and families. Group therapy is one type of treatment for people who may want extra help because of health issues. Teens who receive group treatment also get to meet other teens who may understand them and have good ideas about how to help them. Parents who participate in a caregiver group also get to meet and learn from other parents of teens that suffer from chronic pain.

Our group will use two treatments that research shows can be helpful for pain management: 1) Cognitive-Behavioral and 2) Acceptance & Commitment Therapies. We hope that this group will help you to learn skills for managing pain and other issues that may be stressful for teens. We also hope that this group will help you and your family to identify things that are important to you (i.e., values) for living a healthy and happy life. If you agree to be in this group you and your parent(s) are encouraged to attend each session. We will also ask you to fill out secure online questionnaires at the beginning, middle, and end of treatment as well as 3-months after the program. You do not have to answer any question you do not want to answer. At the end of the study, we hope you will feel that the CAPTIVATE group was helpful for you, and we also believe that your time will help us to improve how we help families like yours in the future.

2. Can anything bad happen to me?

It is up to you to decide if you want to be in this group. While nothing bad can happen to you, you will get help at the same time as other youth 12 to 18 years old. You will also be asked to spend one afternoon per week at our Clinic along with a parent (who will receive help in another group). Seeing other teens while getting help each week may 1) make you aware of what you say or do in the group and/or 2) take away time from other activities. Our team is happy to answer your concerns and questions, if you have any.

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3. Can anything good happen to me?

You may feel good about helping with research for teens with pain. You may also like meeting with, talking to, and learning from other teens like you. Last, you may learn – and start using – ways to cope with discomfort. Coping with discomfort means using skills to help the pain so that you can enjoy your life. You may learn skills like how to change thoughts, deal with feelings, and *do* what is important to you even if you still have pain.

There are no other known benefits. If you agree to do this study, you will express how you feel about your pain, and what you do about it. We will study and share what we learned from you and the group to help other kids with pain in the future, and can share those results with you if you would like. We believe that what we learn from you will help providers (e.g., doctors, therapists) improve treatments they offer to you and others that suffer from chronic pain.

4. Do I have other choices?

Of course! Being in this study is *your* choice, and you can stop this study at any time. The other choice is not to participate, and this is okay with us. It will not affect how we take care of you.

5. Will anyone know I am in the study?

Your participation in this study will be kept confidential (secret). No one but our team and the other families in CAPTIVATE will know that you are in this study. We will have all teens and parents set up "Privacy Rules" specific to their group at the start of CAPTIVATE. Generally, <u>no one</u> in the group will be allowed to share anything with anyone outside the group. Even your parents will not know how you answer your questionnaires or what you say each week in the teen group – unless you want them to. If we have to tell them something to keep you healthy and safe we will talk to you first.

6. What happens if I get hurt?

It is very unlikely that you will get hurt because of this study.

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7. Who can I talk to about the study?

If you have any questions about or problems with the study you can contact the Protocol Director, Dr. Samantha Huestis at (650) 736-3482 or Protocol Co-Director Dr. Rashmi Bhandari at (650) 724-5333.

If you have questions about the study but want to talk to someone else who is not a part of the study, you can call the Stanford Institutional Review Board (IRB) at (650) 723-5244 or toll free at 1-866-680-2906.

8. What if I do not want to do this?

Being in this study is voluntary, meaning you can choose to be in the study or not. It is 100% up to you and your parents/caregivers. Even if you decide to do the study and then change your mind, that is okay. Our medical team will continue to work with you and help you.

SIGNATURE

If you ag	gree to be in this study, please s	ign here:
	Printed Name of Child/Youth	 Date
	Signature of Child/Youth	Date
	Signature of Researcher	 Date

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