

University of California, Los Angeles

CHILD ASSENT FORM (ages 9-12) TO PARTICIPATE IN RESEARCH

The Child Bipolar Disorder Network (CBN):
A Collaborative Treatment Study of Youth with or at High Risk for Bipolar

1. My name is _____.
2. We are asking you to take part in a research study because we are trying to learn more about how to help children who have wide mood swings that are sometimes the early signs of bipolar disorder.
3. If you agree to be in this study, several things will happen:

First, you will come in for a 2- or 3-hour interview (online via Zoom or at UCLA) to see if the study is right for you. We will ask you questions about your feelings and moods, such as if you are happy or sad, and about problems you may have in school or at home. You will also be asked to fill out questionnaires about these topics. You and your family will be paid \$40 for your time.

You will also meet with a medical doctor who specializes in treating kids who have mood problems. This doctor may recommend things to help with your mood, such as medications or talking to a therapist.

If you are eligible for the research study, we will ask you to do the following:

- a) **Blood test:** There are a couple of parts to a blood test. First, a specialist will wrap a rubber band tightly around your arm. Next, they will clean your skin with an alcohol wipe. Then, they will do a small poke with a needle to get a little blood (about 5 teaspoons) into a tube. You can have your parent or guardian there with you during the blood test.

The blood test is optional. If taking part in a blood test is OK with you, please put your initials under "Part 1" below.

- b) **Follow-up visits:** You will return for two follow-up visits (either online via Zoom or at UCLA), one in 6 months from now and one in 12 months. During these 1-2 hour visits, we will ask you questions and ask you to fill out questionnaires about your mood, how you are doing in school, and how well you get along with others. You will be paid \$20 for each visit.
- c) **Web Surveys.** At the initial visit, and again at 6 and 12 months, you will receive daily texts for 6 days prompting you to complete a brief survey about your mood. These prompts will come every few hours. The surveys will take about 5 minutes to complete, and you will be paid up to \$30 for each of the 6-day periods in which you complete all the surveys.

- d) **Video Recording.** We would like to record our interviews with you so that members of our team can learn how to do these interviews properly. If videotaping is OK with you, please put your initials under “Part 2” below.
- e) **Follow-up.** When you finish your 12-month visit, we will give you and your parents recommendations for health services if you need them. We are asking your permission to be contacted up to 5 years after the study has ended for a brief phone interview (15-20 minutes) about your progress. You can always decide at the time if you do not want to participate in the interview. If this is OK with you, please put your initials under “Part 3a” below.

We are also asking your permission to be contacted in the future to see if you would be interested in joining other UCLA studies. You can decide whether or not you want to participate in other studies later. If this is OK, please put your initials under “Part 3b” below.

4. You may feel uncomfortable or nervous about answering some of the questions. Also, your answers to questions about using illegal drugs may be harmful to you if they become known outside the research study. You don’t have to answer any questions you don’t feel comfortable answering.

Information about you, such as your name and address, will be kept private. However, if you tell us that someone is hurting you or hurting other children, we have to report that information to Child Protective Services.

You may feel brief physical discomfort during the blood draw. This discomfort will be like when you receive a shot or get your blood drawn at a regular doctor’s visit. You will not get any direct benefit for yourself from having these tests, but we hope to learn more about how factors in children’s blood relate to their mood problems.

We will be sending you text messages that prompt you fill out online surveys. Text messages in this study will not include any of your personal information, like your name, age, or birthdate.

5. By participating in the study, you may learn more about your different mood states and how to deal with them. You may also learn what can help with mood problems, such as medications or therapy. You and your family will be paid for your participation in the interviews and online surveys.
6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say “yes”, you can still decide not to do this.
7. If you don’t want to be in this study, you don’t have to participate. Remember, being in this

study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop.

- 8. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call Dr. Miklowitz, the study director (310-267-2659) or ask us next time.

If you have concerns or questions about the study and want to talk to someone not on our team, you may contact the **UCLA Office of the Human Research Protection Program (OHRPP)** by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

- 9. Signing your name at the bottom means that you agree to be in this study. Your doctors will continue to treat you whether or not you participate in this study. You and your parents will be given a copy of this form after you have signed it.

NAME OF STUDY PARTICIPANT

Name of Participant

Signature of Participant

Date

Part 1:

_____ **YES** I AGREE TO HAVE A BLOOD TEST

_____ **NO**, I DO NOT AGREE TO HAVE A BLOOD TEST

Part 2:

_____ **YES** I AGREE TO HAVE MY VIDEOTAPES SHARED WITH OTHER RESEARCHERS

_____ **NO**, I DO NOT AGREE TO HAVE MY VIDEOTAPES SHARED

Part 3a:

_____ **YES**, I AGREE TO BE CONTACTED IN THE FUTURE (UP TO 5 YEARS AFTER THE STUDY) TO BE INTERVIEWED ABOUT MY PROGRESS

_____ **NO**, I DO NOT AGREE TO BE CONTACTED IN THE FUTURE (UP TO 5 YEARS AFTER THE STUDY) TO BE INTERVIEWED ABOUT MY PROGRESS.

Part 3b:

_____ **YES**, I AGREE TO BE CONTACTED IN THE FUTURE ABOUT OTHER RESEARCH OPPORTUNITIES

_____ **NO**, I DO NOT AGREE TO BE CONTACTED ABOUT OTHER RESEARCH OPPORTUNITIES

SIGNATURE OF PERSON OBTAINING CONSENT

In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Name of Person Obtaining Consent

Contact Number

Signature of Person Obtaining Consent

Date