University of California, Los Angeles

**PARENT CONSENT / YOUNG ADULT CONSENT (ages 18 to 19) /
YOUTH ASSENT (ages 13 to 17) / PARENT PERMISSION FORM TO PARTICIPATE IN RESEARCH**

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

In the sections that follow, "you" refers to the youth who is being approached about the research study, except where "parent" is indicated. Parents are asked to provide permission for their child's (ages 9-17) participation and also consent to their own participation in the research study.

Why is this research study being done?

Dr. David Miklowitz of the UCLA Semel Institute for Neuroscience and Human Behavior is conducting a research study on youth with bipolar spectrum disorders. You are being approached as a possible participant in this study because you may have challenges with mood, such as significant swings between high and low moods, that are sometimes consistent with bipolar disorder. Your participation in this research study is voluntary.

This research study aims to examine how best to identify and treat kids and teens with or at high risk for bipolar disorder. This study is sponsored by the Baszucki Brain Research Fund and is taking place across four different universities and medical centers, including UCLA, University of Pittsburgh Medical Center, Virginia Commonwealth University, and University of Colorado Anschutz Medical Campus. At UCLA, we are planning to invite 20 participants (ages 9 to 19) and their parents to participate in the study. We are planning to enroll 80 youth across all of the sites.

The study will begin with an initial visit to determine if the study is right for you. Eligible families will be asked to return for a follow-up visit 6 and 12 months later.

What happens if I take part in the research study?

If you decide to be in this study, several things will happen:

1. Initial research interviews: The initial study visit will consist of an interview conducted by a psychologist or social worker on the CHAMP clinic staff. This interview will occur during one or more appointments at the UCLA Child and Adolescent Mood Disorders Program (CHAMP) clinic or using a secure online telehealth platform (e.g., Zoom) if more convenient for you. You and your parent(s) will each spend about 3 hours with our staff

talking about your mood problems (like feeling sad, anxious, or afraid), problems you may have had with friends or other family members, or whether you have ever had any thoughts of harming yourself. You will also be asked about doing things that are against the law, like taking drugs. Some of the questions concern the severity and frequency of certain mood symptoms, like how often you feel depressed or anxious.

2. Psychiatry evaluation. If the results of the first interview suggest that you have had high and low moods that are consistent with bipolar disorder, a study psychiatrist (a medical doctor) will conduct a separate interview with you and your parent(s). The purpose of this second evaluation is so to determine whether you may benefit from medications. If the study psychiatrist concludes that you would benefit from medications, and you and your parent(s) agree that medications are appropriate, then you will be offered medication management sessions from a study psychiatrist for the year-long study. This study does not require that you take any psychiatric medications.

   The treatment offered in the study will be similar to what you would receive from a psychiatrist in the community. If you prefer, you may pursue medication treatment from a doctor with no connection to the study. In either case, you (or your health insurance policy) will be responsible for the costs of these psychiatry sessions, your medications, and any necessary laboratory tests.

   The diagnostic interview and psychiatric evaluation will help the research team determine whether you are eligible for the study. If you are not eligible, we will help you find appropriate care outside of the study.

   If you are eligible, then you will be asked to participate in the following:

3. Questionnaires. You (parent(s) and teen) will be asked to fill out questionnaires regarding your own mood and functioning, including whether you or anyone else in the family has had any history of bipolar disorder, depression or substance or alcohol abuse. You will be asked about problems in school, with peers, or in family relationships.

4. Web-based surveys. You (parents) will be asked to report on your child's mood, behavior, and functioning through weekly web-based surveys for one year. These surveys can be completed on a smartphone or a computer.

   For the week following the initial study visit, and at 6 and 12 months, you will be asked to complete web-based surveys for a period of 6 days. Specifically, the study team will be sending you 3-6 daily texts prompting you to complete a brief web-based survey about your moods, such as how strongly you feel certain emotions, such as being sad, happy, or angry. The survey will take about 5 minutes to complete, and you will be compensated for your time and effort.

5. Blood draw. You (teen) will also be asked to complete a blood draw (either occurring on the same day as the study interview or a subsequent day). For UCLA, blood draws will occur on the Westwood UCLA campus by licensed phlebotomists (specialists with blood draws) or experienced medical staff. The clinician will clean your skin and 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 if you like. Blood samples will be used to test for levels of inflammatory cytokines, a measure of immune responses, which are being investigated in this study as predictors of mood problems and how they respond to treatment. The blood test is optional. If taking part in the blood test is OK with you, please check "Yes" on the line under "Blood Test" at the end of this form.

6. Follow-up research assessments: You (parent(s) and youth) will be asked to complete 2 follow-up research assessments that include interviews and questionnaires about your/your child's symptoms and the family's functioning. These will occur at 6 and 12 months. Your total participation in the study lasts 12 months. Follow-up visits will either occur at the UCLA CHAMP clinic or may occur online (via Zoom) if more convenient for you.

How does this affect my or my child's ongoing treatment?

You should inform your current doctors or other health care providers if you decide to participate in this research study. If you are receiving any type of psychotherapy, you can continue in this therapy without interruption. If you are seeing a psychiatrist or primary care physician for psychiatric medications, our study psychiatrist can communicate their findings and treatment recommendations to your doctor. To allow this communication, you will need to sign a HIPAA research release of information form.

What are my responsibilities as a participant in the research study?

You should:

- Keep your study appointments. If it is necessary to miss an appointment, please contact the Champ Research Coordinator at 310-267-4901 to reschedule as soon as possible.
- Complete your web-based surveys when prompted via text-message.
- Ask questions of the research staff when you have them.
- Tell the research staff if you change your mind about staying in the study.
- Notify the research staff if you are considering taking part in any other research study or seeing a different doctor or therapist.

What happens if I withdraw from the research study?

You are free to withdraw your consent and discontinue your participation in this study at any

time. Your decision to withdraw will not affect your ability to receive any other medical care and you will not lose any benefits to which you would otherwise be entitled. You will be compensated for the parts of the study you completed.

At the discretion of the study director (Dr. Miklowitz), participants may be discontinued from the study for any of the following reasons:

- Failure to follow study instructions or appear for scheduled appointments
- Refusing to complete study interviews or questionnaires
- Using drugs or alcohol regularly
- Continuing in the study could be harmful to you
- The study is cancelled by the study sponsor (Baszucki Brain Research Fund)
- Other administrative reasons

You will be told in advance if such a decision is being considered. If you are withdrawn from the study, you will continue to be offered treatment through your health providers. You will be responsible for the costs of your own care. Referrals to other providers or specialty programs will be provided if you wish.

What are the possible risks or discomforts I may experience from this research study?

There are no significant risks to you or your family members from the research assessments or web-based surveys. You may have some anxiety or discomfort in answering some of the interview questions. The responses to questions concerning illegal drug use or other activity may be harmful to you if they became known outside the study. We do not intend to disclose this information. You do not have to answer any questions that you do not feel comfortable answering.

You may also experience brief physical discomfort associated with the blood draw. Any participant who has an adverse reaction to a blood draw will be treated on site. At UCLA, the blood draws will occur either at the Cousins Center for Psychoneuroimmunology (which has been conducting these studies for many years) or in a laboratory at the UCLA Semel Institute by a trained, licensed phlebotomist. Participants may experience brief anxiety related to the blood draw. You will be accompanied to the blood draw by a study staff member and are welcome to have a parent with you to help alleviate any anxiety you experience prior to or during the blood draw.

Prompts to fill out online surveys will be sent through text message. Because text messaging is not secure or encrypted, there is a chance that messages could be intercepted. Text messages in this study will not include any identifiable personal information and only involve requests and reminders to complete online surveys.

As this study involves the use of your identifiable personal information, there is a chance that a

loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see the "How will my privacy and confidentiality be protected?" section below).

What are the potential benefits of participation?

The information obtained from the clinical interviews, study questionnaires and medication evaluation may help you to obtain a more definitive diagnosis and get better treatment, either within or outside the study. All participants will receive support, information, and referrals for care in the community as needed. The study staff will provide crisis counseling until such referrals have been contacted and treatment initiated.

All young participants will receive a pharmacological evaluation from psychiatrists who are experts in childhood mood disorders. Parents may gain a greater knowledge of how to cope with their child's mood swings and resolve family conflicts, which may improve parents' own mood states and decrease their own distress. All young participants and parents will receive support, help in solving problems, advice, reassurance, and information as needed from project staff members for the year-long study period. The results of the diagnostic assessment may be useful in informing treatments received after the child finishes participation in the study.

Successful implementation of this study may lead to the better identification, diagnosis, and treatment of youth with or at risk for bipolar disorder.

Participation may also involve additional risks listed above. If you decide to take part in this study, you should understand that there is no guarantee that your (your child's) health will improve.

Will I be paid for my participation in this research study?

Participants will be financially compensated for completing the research assessments. You will be paid $40 for the initial research visit and $20 for each hour-long follow-up visit at 6 and 12 months. You will also earn up to $30 for the 6-day web-based surveys during each of the study assessment periods (initial visit, 6 and 12 months). Over the 12 months, you can earn up to $170. If you decide to stop the study early, you will be paid for those research assessment sessions that you completed up to that point.

What alternatives are there to participating in the research study?

Other providers in the community conduct psychiatric evaluations and provide treatment for mood disorders in children. These evaluations and treatments may include interviews, various medications, group therapy, individual therapy, or family therapy. You may also choose to get no evaluation or treatment. You should talk about other treatments with your existing health care providers. Make sure that you understand all of your choices before you decide to take

part in the study. You may withdraw from the study without losing alternative treatments available through your medical providers. These other treatments will be available to you during and after the study. If you wish, the project staff will give you referrals to other providers.

What are my rights if I take part in the research study?

You should not feel required to participate. Your questions should be answered clearly and to your satisfaction. Your signature on this consent form indicates that this project has been explained to you, and in language you can understand; and that you have been encouraged to ask questions, both now and in the future.

You will be told of any important new information that is learned during the course of this research that might affect your willingness to continue participating in this study.

Use of Videotapes for Research

All research interviews with you and your family members will be recorded on a video server. We are asking your separate permission, indicated by checking the appropriate checkbox listed at the end of this form, to allow these digital audio or video files to be used for research. If you allow us to do this, then your video files may be viewed by a supervising clinician and/or a member of our research team to assure that the interview meets a high standard. They will not discuss the content of these tapes with anyone outside of the team.

The digital videotapes will be identified only by a number and not by your name, and kept only for the purposes of research. They will be kept on password-protected laboratory personal computers, housed in the CHAMP Clinic research rooms at UCLA. A list with the pairings of names and participant numbers will be kept on a separate password-protected personal computer to which only Dr. Miklowitz and research staff will have access.

If you would like, you can listen to any of these tapes. If you want any of them to be erased, the staff members will do this. Otherwise, the tapes will be kept for ten years after the study has been completed and then erased.

How will my privacy and confidentiality be protected?

Your identity will be kept as confidential as possible. Data records, publications and presentations that result from this study will not identify you by name or other personally identifying information, such as social security number, address, email, or telephone number. Instead, you will be assigned a code number, and all of your questionnaires, interviews, and video- or audiotapes will be identified by this code. Information about the code will be kept in a secure location and access to the list of names and code numbers will be limited to only members of Dr. Miklowitz's UCLA research team.

Information that you provide to the research staff during individual interviews will not be shared with others unless there are significant safety concerns.

Information about you and your child is protected by a federal Certificate of Confidentiality from the National Institute of Health. This means that we cannot release or use information about you or your child for in any legal action or suit, including as evidence, unless you say it is okay. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings (an example would be a court subpoena). The Certificate allows us to use information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect information we share with them.

The Certificate DOES NOT prevent your information from being shared in certain circumstances in which we may not be able to keep your participation in the study or related information fully private, such as when:

- You or your family members voluntarily release information about your participation in the study or related information to others
- You consent to release of information to people you specify (for example, if you sign release forms for school, employment, insurance or medical care)
- If a sponsoring US federal or state government agency requires information as part of evaluating programs and checking records
- If the Food & Drug Administration requires information as part of overseeing the safety of drugs, devices or other products
- When the team is required to report possible intent to harm yourself or others, child abuse or neglect, elder abuse or neglect, or some communicable disease cases. If you give us any information about child abuse or neglect, or any circumstances which might reasonably result in abuse or neglect, we are required to report that to Child Protective Services. If you tell us that you or they are going to physically hurt someone, we are also required to report that to the police and notify the potential victim.

All web-based surveys will be provided through the "Chorus" online platform at UCLA. Chorus is a web platform that is hosted on a secured, SOC2 Type 2-compliant server, and is HIPAA-compliant. All data sent to or from the Chorus apps are transmitted over encrypted, industry-standard connections like SSL (secure socket layer). The server is protected using standard practices including being located behind a network firewall and accessible only by designated users. Data are regularly backed up. No data are stored locally on user's devices that access Chorus apps. Chorus has been approved by the UCLA Office of Information Security for use in research projects including those that collect protected health information.

In the future, data collected for this study may be shared with other researchers for other studies that are unknown at this time. Any data shared with other researchers will not include your name or other personal identifying information.

The research team, authorized UCLA personnel, the study sponsor (Baszucki Brain Research Fund), and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study for safety and ethical reasons. Any records provided to these authorized, non-UCLA personnel will not contain identifiable information about you.

What other things should I consider before participation?

Any specimens (e.g., blood) obtained for routine lab testing will be discarded or destroyed once they have been used for the purposes described in the protocol.

Are there any costs associated with participation?

There are no direct costs to you or your family for participating in the research interviews or evaluations of this study. We do not anticipate that participating in the study will interfere with any health insurance benefits to which you are entitled.

The study will pay for the cost of administering the blood tests that are part of the study, as described in this consent form. The costs of medications and meetings with the psychiatrist will be your responsibility.

Will I be contacted again in the future?

At the end of your participation in this study, you will be provided with recommendations for ongoing clinical care. If you check the appropriate box below, you will also allow us to contact you up to 5 years after the 1-year study period for a phone interview (no longer than 1 hour) about your (your child's) progress. You can decide at that point if you no longer want to be interviewed or contacted for future interviews, and your decision to not participate or be contacted in the future will in no way impact your clinical care at UCLA.

If you check the appropriate box below, you also allow us to contact you in the future if there are other UCLA research studies for which you might be eligible. Your decision to participate or not participate in any research study will in no way impact your clinical care at UCLA. If you would like to be contacted in the future about other UCLA research studies, please check "Yes" on the line under "Future Contact" at the end of this form.

Who can answer questions I might have about the research study?

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment; or if you feel you have been hurt by being a part of this study, or need immediate assistance, please contact Dr. David Miklowitz, the Study

Director, at (310) 267-2659.

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights as a research participant, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

Signatures of Parent and Child

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

BY SIGNING HERE, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH DESCRIBED.

_____
Name of Child Participant (**ages 13 to 17)**

_____ _____
Signature of Child Participant Date

_____
Name of Adult Participant (**ages 18 to 19)**

_____ _____
Signature of Adult Participant Date

Parent or Legal Guardian

_____
Name of Parent or Legal Guardian

_____ _____
Signature of Parent or Legal Guardian Date

Blood Testing

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

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

Future Contact

_____ **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 INTERVIEWD ABOUT MY PROGRESS

_____ **YES**, I AGREE TO BE CONTACTED IN THE FUTURE ABOUT OTHER RESEARCH STUDIES FOR WHICH I MAY BE ELIGIBLE

_____ **NO**, I DO NOT AGREE TO BE CONTACTED IN THE FUTURE ABOUT OTHER RESEARCH STUDIES FOR WHICH I MAY BE ELIGIBLE

Use of Videotapes and Audiotapes

_____ **YES,** I AGREE TO HAVE MY VIDEOTAPED INTERVIEWS USED FOR RESEARCH PURPOSES

_____ **NO**, I DO NOT AGREE TO HAVE MY VIDEOTAPED INTERVIEWS OR SESSIONS USED FOR RESEARCH PURPOSES

Signature of Person obtaining consent

I have explained the research to the subject or their parent or legal guardian and answered all of their questions. I believe that they understand the information described in this document and freely consent to participate.

_____	_____
Name of Person Obtaining Consent	Contact Number
_____	_____
Signature of Person Obtaining Consent	Date