RESEARCH PARTICIPANT CONSENT INFORMATION FOR ONLINE SURVEY

STUDY TITLE: OPEN EVALUATION OF THE SUPPLEMENT N-ACETYLCYSTEINE (NAC) FOR CHILDREN WITH SUBTHRESHOLD MOOD AND ANXIETY SYMPTOMS

VCU INVESTIGATOR:
Dr. Ekaterina Stepanova, MD, PhD
Department of Psychiatry
Division of Child and Adolescent Psychiatry
804-682-8794
Ekaterina.Stepanova@vcuhealth.org

NOTE: In this consent form, "you" always refers to the research participant

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please contact the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may print a copy of this consent information to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

WHY IS THIS STUDY BEING DONE?

This research is being done to collect information on how a range of mood and behavior disorders in children are being treated and how successful the treatments are in managing the disorders.

We want to collect this information on a large number of children which may help doctors and researchers to better understand how children currently receive care for mood disorders. To date, there is very little information that has been collected about children in the 2-12 age range with these disorders. They are usually excluded from clinical research studies because of their young age. We hope that this information will help researchers to better design and conduct future research studies on the effect of medication and other therapies.

Parents of children ages 2 to 12 with symptoms of a mood, anxiety or behavioral disorder may join this study. One or both biological parents may also participate in the study if either of them has been diagnosed with depression or bipolar disorder, even. though their child is currently well and has no troublesome mood, anxiety, or behavioral symptoms.

Parents must have access to the internet and speak English because the forms and communications, as well as consents, will be completed on a computer and are only in English.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

If you agree to be in this study, we will ask you to do the following things:
You will complete questionnaires/forms using the computer-based CHILD NETWORK website. All data collection and communication about the study will occur online, via the secure, HIPAA compliant REDCap platform linked on the Bipolar Network News (BNN) website.

One Time only:

- Background Demographics and Family History (D-FamilyHx) form which will take about 10 minutes to complete.

One Time Each Year:

- Screening questionnaire for childhood mood and behavioral disorders called the K-M3-97 to evaluate changes in a child's symptom profile over time. This will take about 20-30 minutes to complete.

On a weekly basis:

- Weekly Symptom Status Report Form where you will be asked to:
    - Rate your child's anxiety, depression, oppositional, ADHD, and manic-like symptom severity.
    - If applicable, enter medication names and doses the participant's child is currently taking.
    - If applicable, include information on side effects and if so, the severity of any side effects.
    - The Weekly Symptom Status Reports will take about 5 to 10 minutes to complete.

Your Reponses to the questionnaires/forms will not impact your child's medical treatment. All treatment decisions will continue to be made by your child's doctor, who is not involved in this study.

You will be able to print out graphs/reports using the information they have entered on the website and may bring them to doctor visits.

Participants will have access to general information provided in the Bipolar Network News, and participation in this study and use of the website may help parents better understand a variety of mental health issues and will provide them with educational information. Initial summaries of the study results will be available on the BNN.
You may send email questions to the study doctor which will be answered by email. If the questions are of general interest to other study participants or those using the Bipolar Network News website, answers to those questions might be posted on the Bipolar Network News website, www.bipolarnews.org.

Your participation in this study will last up to 5 years. Approximately 4000 individuals will participate in this study.

WHAT ALTERNATIVES ARE AVAILABLE?

This study does not involve treatment, but the Bipolar New Network website has instructions for mood charting to collect data on your child's symptoms to bring to their doctor.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

Your Reponses to the questionnaires/forms will not impact your child's medical treatment. All treatment decisions will continue to be made by your child's doctor, who is not involved in this study.

You will be able to print out graphs/reports using the information they have entered on the website and may bring them to doctor visits.

The benefits to the greater community (including the participants), is that participation in the study may: 1) reveal new preliminary treatment findings; 2) identify new areas of drug safety concerns; 3) help in the design of future studies; 4) identify areas of great unmet need; and 5) help in advocacy of more treatment research for children with
mental health disorders.

Participating in this study, may help others in the future. As information is collected, it will be analyzed and presented at meetings as well as published in journal articles and the BNN newsletter at www.bipolarnews.org

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

Questionnaires may contain questions that are sensitive/personal/upsetting/ offensive/disturbing/etc. in nature. You may refuse to answer any question that makes you feel uncomfortable.

Psychological Risks:
This study involves parents who normally observe their child's behavior so it would be very unlikely that there would be additional psychological or emotional risks. This study would only provide a more detailed way of rating and keeping track of the behavior.

Discomfort:
There is extra time required to complete the weekly mood/behavior ratings. The weekly mood, medication, and side effects documentation will take approximately 10 minutes each week. Filling out the initial forms (D-FamilyHx and K-M3-79) described above will take about 45 minutes.

You do not have to answer any question you do not want to answer.

Confidentiality of information:
Every effort will be made to keep all participant information completely confidential, so there is extremely minimal risk of any breach in confidentiality. However, there is always a risk of identifiable information getting released. All information will be entered into a secure data system available only to the study staff.

In addition, when the collected information is analyzed and published, only group study information will be included. In other words, no individual parents and children will be identified.

This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study.

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information will be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services or the Federal Food and Drug Administration

Any information provided to you will be your responsibility to keep private and protected once it has been given to you.

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

All information you provide will only be associated with an ID number and not with a name. When any data analysis is performed, your associated email will be removed prior to the analysis of the data.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☐ Complete health record	☐ Diagnosis & treatment codes	☐ Discharge summary
☐ History and physical exam	☐ Consultation reports	☐ Progress notes
☐ Laboratory test results	☐ Medical imaging reports	☐ Imaging films/scans/pictures
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	
☐ Information about mental health	☐ Information about sexually transmitted diseases	

☒ Other physical or mental health information (specify): This study will use mental and other health information that you provide about your child in the course of study activities.

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Data Coordinators
- Research Collaborators
- Data Safety Monitoring Boards

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
Any identifiable information associated with the data you provide over the course of the study will be removed when the study ends or when you choose to withdraw.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at Dr. Ekaterina Stepanova at 1308 Sherwood Avenue Richmond, VA 23220

WHAT ARE THE COSTS?

There will be no costs to participant as a result of participation in this study.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Ekaterina Stepanova, MD, PhD
804-682-8794
Ekaterina.Stepanova@vcuhealth.org
and/or
Sebastian Nair
804-628-8737
Sebastian.nair@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298

(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

If you have any questions, please contact the study team before taking the survey.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered.

OPTIONAL MAINTENANCE OF CONTACT INFORMATION FOR FUTURE STUDIES

We may have other studies like this one that you might be interested in. With your permission, I would like to keep your name and email address in our research database so that we could contact you when we begin any new studies. This information would not be stored with any of the information you provide in this interview.

Do you give permission for your contact information to be saved and used to contact you about future studies?

YES

NO