RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: The Childhood Mood Disorder Initiative

VCU INVESTIGATOR: Ekaterina Stepanova, MD PhD

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 ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.**

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.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

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?

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:
    - Log on to the Child Network each Sunday (if at all possible)
    - 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 alternative treatments or procedures 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 risks and benefits of participating?

Risks to the participants will be minimal.

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.

If you get bored when you are completing the questionnaires, you can return to them at a later time. 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 low risk of identifiable information getting released. All information will be entered into a secure data system available only to the study doctors of this project—Drs. Ekaterina Stepanova, Robert Findling, and Robert Post. Any other use of information beyond this secure system would be given a Network code number.
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.
There is a potential direct benefit from participating in this study. The repeated weekly mood, medication, and side effects ratings may help parents and treating clinicians keep track of and assess medication effects.

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 ARE THE COSTS?
There is no cost to you to participate in this study..

WILL I BE PAID TO PARTICIPATE IN THE STUDY?
No

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?
If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

WHY MIGHT WE TAKE YOU OUT OF THE STUDY EARLY?

If you do not respond with weekly follow-up ratings, a study doctor or staff member will send out up to 3 reminder emails after each missed rating. After four weeks in a row, of missing follow-up and after six months enrolled in the study, you will be considered "lost to follow-up" and no longer in the study. You will be notified that you are no longer in the study as the weekly ratings will no longer be sent to you. If you decide to stop participating in the study or you are taken out of the study early, your health information that has already been collected may be used in analyzing group study data, but all data will have identifiers removed and your contact information will be removed from 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 may be kept in these databases according to VCU's policies (i.e. for a minimum of 5-6 years). It is 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.
In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

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.

RECONSENT INFORMATION

Due to this study being moved from Johns Hopkins University to Virginia Commonwealth University Health System, we are asking for you to go through the consent process again for participation in this study.

All previously collected data will be moved to VCU's REDCap website. Data previously collected will be migrated to the new platform, if you do not agree to having your contact information or any potentially identifying information moved to the new platform either email or call the study staff at the listed below and we will remove your contact information and any identifying information from the database. Alternatively, after four weeks in a row of missing follow up or without undergoing the reconsent process and after six months enrolled in the study you will be considered "lost to follow-up" and your contact information and any identifying information will be removed from the database.

All new data will be collected on REDCap, REDCap is a secure, HIPAA-compliant online database that consists of password protected accounts. Demographic, psychiatric, and behavioral data will be stored in REDCap.

REDCap also maintains a built-in audit trail that logs all user activity and pages viewed by every user, including contextual information (e.g., the project or record being accessed), data entry, data export, modifying a field, running a report, or adding/modifying a user. The built-in audit trail in REDCap allows administrators to be able to determine all the activity and all the data viewed or modified by any given user. The REDCap administrator is also available to assist with technical support on research projects. All requests for analysis of datasets must be approved by the PI and site PIs before they are accessed from REDCap.

Study personnel will perform ongoing quality checks of the database, monitor the data correction process, and assist study staff with all aspects of system usage and other programming and IT needs.

Data storage and access procedures will be in full compliance with VCU Health data security policies. All study-related data will be collected in Redcap database. Consents/assents will be collected in paper format and a copy will be given to the participants. Paper consents/assents will be stored under double lock. No identifiable information will be shared outside of the study team.

Data is being collected for research purposes only and will not be associated with or derived from a healthcare service event (treatment, payment, operations, medical records) at VCU HS. The research data will not be entered into VCU HS medical or VCU dental records.

Certificate of Confidentiality

To help us protect your privacy, we have applied for a Certificate of Confidentiality from the National Institutes of Health. If this certificate is obtained, it will offer the protections describedhere. A Certificate of Confidentiality helps the researchers keep your information private. For
example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

We may have other studies like this one that you might be interested in. With your permission, I would like to keep your 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.

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. - ekaterina.stepanova@vcuhealth.org

and/or

Sebastian Nair, Clinical Research Coordinator – sebastian.nair@vcuhealth.org - (804) 628-8737

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
Phone: (804) 827-2157
https://research.vcu.edu/human-research/hrppirb/research-participants/

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

Do you give permission for your contact information to be saved and used to contact you about future, related studies, during the duration of this study?

☐ YES

☐ NO

☐ 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. By checking this box, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

_____

Name of Child/Youth

_____ _____

Name of Parent/Legal Guardian Date

_____ _____

Signature of Primary Investigator (If different from above) Date