A Randomized Controlled Trial of Quetiapine for the Treatment of Youth With Co-Occurring Substance Use Disorders (SUDs) and Severe Mood Dysregulation (SMD)

NCT02845453

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RESEARCH CONSENT FORM

Basic Information

Title of Project: A Randomized Controlled Trial of Quetiapine for the Treatment of Youth With Co-Occurring Substance Use Disorders (SUDs) and Severe Mood Dysregulation (SMD)

IRB Number: submission H-39577

Principal Investigator: Amy Yule, MD
E-mail: Amy.yule@BMC.org
PI/study mailing address: 720 Harrison Ave Suite 915, Room 910 Boston, MA 02118

Study-Related Phone Numbers: Regular business hours: 617-699-5899, 24 hours: 617-414-1990

Overview

We are asking you to allow your child to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you and your child should expect if you agree to allow your child to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to allow your child to join the study. We are doing the research to find out if a medication called quetiapine (also known as Seroquel) can help youth with substance use disorder (SUD) and severe mood dysregulation (SMD). If you agree, your child will take either quetiapine or placebo for 8 weeks. They will also be encouraged to engage in behavioral therapy through the Boston Medical Center clinical program, CATALYST, if they are not already engaged in therapy elsewhere. Your child will be in the study for 10 weeks if you and your child decide that your child will stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are from the side effects of the study drug and your child will be asked to disclose sensitive, personal information. You will find more information about risks later in this form.

Your child might benefit from being in the study because their SUD and/or severe mood symptoms may improve. You will find more information about benefits later in this form.

Your child could get these benefits without being in the study by engaging in therapy or psychiatric care. You will find more information about alternatives later in this form.

Your child's doctor may also be an investigator in this research study. Being an investigator means your child's doctor is interested in both your child and the study. Your child may want to get another opinion about being in the study. You and your child can do so now or at any time during the study. A doctor

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who is not part of this study could give you and your child their opinion about being in the study. You and your child do not have to agree to be in this study even though it is offered by your doctor.

Purpose

We are doing this research study to find out if a medication called quetiapine (also known as Seroquel) can help youth with SUD and co-occurring SMD. SMD includes bipolar spectrum disorders, disruptive mood dysregulation disorder, and mood disorder not otherwise specified. We want to find out if quetiapine is beneficial in reducing substance use and mood symptoms in individuals with SUD and SMD.

The U.S. Food and Drug Association (FDA) has approved quetiapine to treat mania in bipolar disorder in adolescents, as well as depression and mania in adults. However, quetiapine is not approved by the FDA to treat co-occurring SMD and SUDs in youth. This is what we intend to study in the current investigation.

We will compare quetiapine to a placebo. The placebo will look exactly like the quetiapine capsules, but will contain no quetiapine. During this study, your child may get a placebo instead of quetiapine. Placebos are used in research studies to see if the study results are due to the study drug or due to other reasons. Your child will be continued on your current medication if it has been helpful to them. However, we ask that your child does not change their medication during the duration of the study. We will also encourage your child to engage in behavioral therapy through the Boston Medical Center clinical program, CATALYST, while they are participating in the study, if they are not already engaged in therapy elsewhere.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful.

We are asking your child to take part in this research study because they have been diagnosed with SUD and SMD. About 56 people will take part in this research study. The American Academy of Child and Adolescent Psychiatry is paying for this study to be done through a grant from the National Institutes of Health-National Institute on Drug Abuse (NIH-NIDA).

What Will Happen in This Research Study

If your child is aged 15-17 and chooses to take part in this study, we will ask them to sign a consent form in addition to the consent form we ask you to sign. If your child turns 18 during the study, we will ask them to sign another consent form before continuing with the study. We will give you and your child a copy for your records.

Because of COVID-19, some study visits will happen virtually using Zoom Videoconferencing software. Your child can use Zoom on their phone, computer or tablet. By signing this form, you and your child agree to take part in both in-person and virtual study visits. In case of scheduling conflicts, or in the event that your child is unable to use Zoom, they will have the option to complete some visits over the phone. The study doctor will speak with your child over the phone and ask them the same questions that he/she would ask if they came to the office.

SCREENING PERIOD

Screening Visit (Visit 1)

Visit 1 will take place at virtually using Zoom videoconferencing. It will take about 1.5 hours to complete this visit. At this visit, we will ask your child questions regarding your mood and substance use to see if they qualify to take part in the study. If they do not qualify, the study doctor will tell them why.

At this visit, we will:

- Review your child's medical and psychiatric history and ask them questions about their symptoms of SUD and SMD.
- Ask your child questions about their substance use and mental health. The interview is in a "yes or no" format and covers questions about mood and substance use.
- Ask your child questions about their height and weight to calculate their Body Mass Index (BMI).
- Ask your child questions about their manic and depressive symptoms.
- Ask your child questions about their race, ethnicity, and family history.
- Ask your child to complete a questionnaire about their type of substance use and frequency over the course of the past month.
- Ask your child to complete a questionnaire about their mood
- Ask your child to sign a release of information for the treatment program where they are/will be receiving behavioral therapy to coordinate their treatment.
- Ask you questions about your child's socioeconomic status, educational accommodations, and past head injuries/trauma.
- We may ask you to fill out two questionnaires about your child's mood.
- Ask your child screening questions for COVID-19 exposure/illness.

Screening Visit (Visit 2)

The second screening visit will take about 2 hours and will be completed at Boston Medical Center. The second screening visit will take place between 1 and 14 days after the first screening visit. At the second visit, we will do some tests and procedures on your child to gather more information and ensure their safety while participating in the study. The study doctor will review the results of these tests and procedures and inform your child if it is unsafe for them to participate.

- Measure your child's vital signs (blood pressure, pulse).
- Measure your child's height and weight to confirm their Body Mass Index (BMI).
- Do a urine drug test with your child for certain types of drugs and breathalyzer for alcohol. The urine drug test includes prescription drugs and illegal drugs like marijuana, cocaine, PCP, and sedatives (habit-forming drugs that make you sleepy and calm).
- Give your child 4 drug tests to administer at home over the next 4 visits and provide an explanation on how to do so.
- Do a urine pregnancy test with your child if they are female and have started their periods (menstrual cycle). Pregnant women cannot take part in the study.

If your child is 16 or 17 years old, we will tell you the result if your child agrees to let us tell you. Even if your child does not agree, the study doctor may decide, based on their age, maturity, or medical condition, to tell you this information.

- Draw blood from your child for laboratory safety tests. This includes tests for HIV and Hepatitis C, tests of how well the liver is working, and tests of blood sugar levels and lipid (fat) levels. We will draw a total of about 2 tablespoons of blood during the entire course of this research study. We may ask your child to fast for several hours before drawing their blood for these tests. Hepatitis and HIV results will become part of their hospital medical record. We will refer your child for medical care if we find they have these infections. By law, healthcare providers must report positive test results for infectious diseases to public health authorities, including the Massachusetts Department of Public Health. These reports are required to identify your child by name.
- Perform an EKG on your child to screen for cardiac disease. An EKG is a test that measures the electrical activity of a heartbeat. Electrodes with stickers are placed on your child's chest, arms, and legs for about 10 minutes.
- Ask your child questions about how they took their medications in the past.
- Ask your child questions about your reasons for using alcohol/substances and coming to treatment, their family members' opinions on your alcohol/substance use, and their friends' drinking/drug use.
- Ask your child to complete 2 questionnaires about their mood.
- We may ask you to fill out a questionnaire about your child's mood.
- Ask your child questions about their mental health. The interview is in a "yes" or "no" format and covers questions about anxiety and attention.
- We will ask your child about any involuntary (unintentional) muscle movements they experience, and the study doctor will perform some tests to examine any possible involuntary movements they may experience.
- Ask your child about their current place of residence where we can mail their study medication.
- Ask your child screening questions for COVID-19 exposure/illness. Take your child's temperature using a no-contact thermometer.

Blood Test Results

We will compare your child's beginning test results, before they have taken the study drug, to the blood test results at the end of the study to see if there are any changes. During the study, these tests will help us know if your child can continue to take part in the study safely. The results of the blood tests will be placed in your child's Boston Medical Center medical record.

Assignment to Study Group

If your child qualifies to take part in the study, we will assign your child by chance (like the flip of a coin) to the quetiapine or to the placebo group. Your child and the study doctor cannot choose your study group. Your child will have an equal chance of being assigned to either group. You, your child and the study doctor will not know which study group your child is in, but the study doctor can find out if necessary.

STUDY DRUG PERIOD

If your child qualifies to take part in the study, we will ask your child to attend a study visit **once per week** for 8 weeks. Two of these visits will take place in person at Boston Medical Center. The remaining 6 visits will take place over Zoom videoconference.

Visit 3

This visit will take about 1 hour and will be completed virtually. During the Week 0 visit (Visit 3) we will:

- Review healthy lifestyle behavior suggestions.
- Ask your child to complete a urine drug test for certain types of drugs and discuss the results of the test.
- Ask your child about their symptoms of SUD and SMD, their overall functioning, and any other symptoms they may be having.
- Ask your child about risky behavior including details about substance use, and sensitive questions regarding their sexual activity.
- Ask your child to fill out 4 questionnaires about their SUD and SMD symptoms.
- Ask your child to weigh themselves if their Body Mass Index was between 30 and 35 at Visit 2.

Taking the Study Drug
The study doctor will explain to your child how to take the study drug. Your child will need to take the study drug either once or twice a day. If your child takes the study drug twice a day, your child will take one dose of the study drug in the morning and one dose in the evening. Please call the study doctor if you or your child have any questions or are ever unsure about how much study drug your child should be taking.

We will mail the study medications to your child in two week supplies until their next in person visit. At that visit we will give your child the remaining 4 weeks supply. Your child will be asked to bring any unused study drug to Boston Medical Center at every in-person visit. We will count the leftover pills at each in-person study visit and ask your child to count the leftover pills during each virtual visit to make sure your child is taking the study drug properly.

The Study Drug Diary
We will give your child a study diary to fill out at home each day. Your child will write down the date and time they take the study drug and any other medications, as well as the dose they are taking. We will ask your child to bring this diary with them to each study visit (in-person or virtual), so we can track their progress.

Visits 4, 6, 8, 10

These visits will take about 30 minutes, and will all take place virtually. At these visits we will:

- Ask your child to complete a urine drug test for certain types of drugs and discuss the results of the test.
- Ask your child about their symptoms of SUD and SMD, their overall functioning, and any other symptoms they may be having. The study doctor will also ask if your child is having any side effects and if they have taken any other medication during the week.
- Ask your child to fill out 1 questionnaire about their SUD symptoms.
- Count unused study drug from the previous week.
- Ask your child to weigh themselves if their Body Mass Index was between 30 and 35 at Visit 2 or Visit 7.

Visits 5 and 9

These visits will take about 45 minutes, and will all take place virtually. At these visits we will:

- Ask your child to complete a urine drug test for certain types of drugs and discuss the results of the test.
- Ask your child about their symptoms of SUD and SMD, their overall functioning, and any other symptoms they may be having. The study doctor will also ask if your child is having any side effects and if they have taken any other medication during the week.
- Ask your child to fill out 4 questionnaires about their SUD and SMD symptoms.
- Ask your child to weigh themselves if their Body Mass Index was between 30 and 35 at Visit 2 or Visit 7.

Visit 7

This visit will take about 45 minutes, and will take place at Boston Medical Center. At this visit we will:

- Measure your child's vital signs (heart rate, blood pressure).
- Measure your child's weight to confirm their Body Mass Index (BMI).
- Do a urine drug test with your child for certain types of drugs and breathalyzer for alcohol.
- Ask your child about their symptoms of SUD and SMD, their overall functioning, and any other symptoms they may be having. The study doctor will also ask if your child is having any side effects and if they have taken any other medication during the week.
- Ask your child to fill out 4 questionnaires about their SUD and SMD symptoms.
- Ask your child to fill out 2 additional questionnaires about their SUD and SMD symptoms.
- Ask your child about risky behavior including details about substance use, and sensitive questions regarding their sexual activity.
- Do a urine pregnancy test with your child if they are female, and have started their periods.
- Collect all unused drug from the past few weeks.
- Collect all medication diaries from the past few weeks.
- Give your child a new supply of the study drug.
- Give your child 4 drug tests to administer at home over the next 4 visits.
- Ask your child screening questions for COVID-19 exposure/illness.
- Take your child's temperature using a no-contact thermometer.

Visit 11 (Final Visit)

This visit will take about 2 hours and will take place at Boston Medical Center. During the final medication study visit, we will:

- Measure your child's vital signs (heart rate and blood pressure).
- Measure your child's weight to confirm their Body Mass Index (BMI).
- Do a urine drug test with your child for certain types of drugs and breathalyzer for alcohol.
- Do a urine pregnancy test with your child if they are female and have started your periods.

- Ask your child about their symptoms of SUD and SMD, their overall functioning, and any other symptoms they may be having. The study doctor will also ask if your child is having any side effects and if they have taken any other medication during the week.
- Ask your child about risky behavior including details about substance use, and sensitive questions regarding their sexual activity.
- Ask your child to fill out 7 questionnaires about their SUD and SMD symptoms.
- We may ask you to fill out 2 questionnaires about your child's mood.
- Draw a blood sample from your child. One vial of blood will be stored until the end of the study to test for quetiapine levels. The blood will be stored in a locked room only accessible by study staff.
- Collect all unused study drug.
- Collect all medication diaries from the past few weeks.
- Ask your child screening questions for COVID-19 exposure/illness.
- Take your child's temperature using a no-contact thermometer.

COVID-19 Safety

For you and your child's safety, study areas will be sanitized with germicidal cleaning wipes and/or spray before any in-person visit. In addition, research staff will wear a mask at all times. Your child (and you if you attend) must also wear a mask at all times. Your child may bring their own mask or we will provide them with a disposable face mask.

Physical distancing will not be possible during certain study procedures like vital signs. However, all other procedures that need to be completed during these visits can be done virtually through zoom with your child on a computer in one office and research staff in another office.

In addition to asking COVID screening questions at Visit 1 and in-person visits, we will also ask your child these questions the day before in-person visits by phone. Questions will ask about possible symptoms, travel, contact with someone who may have had COVID-19 and if you have been confirmed or suspected to have COVID-19.

Audiotape Recordings

We may make audiotape recordings while you and your child are answering some of our study questions during the study. These recordings will help us check the way that study staff members ask questions in this study. Each recording will be labeled with your child's initials and an identification number and not their name in order to maintain confidentiality. We will store these recordings on a computer protected by a password.

Text Message Reminders

Text messages by mobile/cell phones are a common form of communication. This research study involves sending your child text messages to remind them of their scheduled appointments. Texting over mobile/cell phones carries security risks because text messages to mobile/ cell phones are not encrypted. This means that information your child sends or receives by text message could be intercepted or viewed by an unintended recipient, or by your child's mobile/ cell phone provider. Since texting is not the most secure method of communication, we remind you and your child not to use texting as a method of communication other than for scheduling appointments.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Boston Medical Center are not responsible for any interception of messages sent through unencrypted text message communications.

- Your child will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Boston Medical Center are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messages will only be read during regular business hours. Texts sent on nights or weekends will not be read until the next business day.

- Text messaging should not be used in case of an emergency. If your child experiences a medical emergency, call 911 or go to the nearest hospital emergency department.

- Your child may decide to not send or receive text messages with staff associated with this research study at any time. They can do this in person or by sending the research number a text message that says "Stop Research Text."

- Your child's agreement applies to this research study only. Agreeing to other texts from Boston Medical Center, for example appointment reminders, is a separate process. Opting out of other texts from Boston Medical Center is a separate process as well.

- It is your child's responsibility to update your mobile/cell phone number with this research study in the event of a change.

By signing this document, you agree that you have had the chance to ask questions about texting with staff associated with this research study, you have been informed of the risks and other information covered above, and you consent to the use of unencrypted text communications associated with this research study.

Leaving the Study Early

Your child can stop taking part in this study at any time. We may stop this study or remove your child from the study at any time if it is necessary and/or in your child's best interest. We may stop your child from taking part in this study for any of the following reasons:

- If your child does not feel well on the study drug.
- If there is new information on the safety of the study drug.
- If your child becomes pregnant during the study.
- If your child's drug use or mood symptoms escalate to the point where a more structured level of care is more appropriate.
- If your child does not follow study guidelines, misses appointments, or does not return unused study drug.
- If your child's weight increases such that their Body Mass Index increases by 1 if…
  1) their Body Mass Index was above 30 at Visit 2 **OR**
  2) their Body Mass Index was under 30 at Visit 2 but above 30 at Visit 7

If your child leaves the study early, we will ask your child to complete all the procedures that are done during the final study visit (Visit 11). We will tell your child how to stop taking the study drug safely. It is important that your child return any remaining study drug if they leave the study. If you want, we will refer your child to another doctor or group in your area. If you would like us to release information to your child's new doctor, you must sign a release of health/medical information form.

Optional Follow-Up Visits (After you complete the study)
After your child finishes the study or if they withdraw early from the study for any reason, we will offer 3 clinical follow-up visits. Your child does not need to come to these follow-up visits; they are optional. During these follow-up visits, the study doctor will ask your child about their symptoms of SUD and SMD. The study doctor will also ask about your child's overall health, and offer treatment guidance. These visits will last about 30 minutes each. These follow-up visits are not part of the study. We offer these follow-up visits to help your child find long-term care for their symptoms of SUD and SMD. We will not charge you for these appointments. However, you will be responsible for the cost (including any insurance co-payment) of medication if it is prescribed.

Medical Records
A notation that your child is taking part in this research study may be made in your child's electronic medical record. Information from the research that relates to your child's general medical care may be included in the record (for example, results of standard blood tests done at the hospital labs). Please ask the study doctor if you have any questions about what information will be included in your child's electronic medical record.

The ways we will protect you and your child's privacy and confidentiality are described in a separate section later in this form.

The research measurements we make are not necessarily the same as tests done by your doctor. We are collecting information on many people to answer our research questions. Not everyone doing the research tests is a doctor or a nurse. Your child or your doctor should not rely on the research measurements to make any diagnosis, treatment, or health planning decisions. If your child or your doctor decides that follow-up tests and treatments are necessary, then your child or their insurance will be billed for the costs.

You will be one of approximately 37 subjects who will be asked to be in the study.

Risks and Discomforts
Taking part in this study may involve risks, some of which are listed below. There may also be other side effects that are not known at this time.

Risks of Taking Quetiapine
The risks of being in this study include the side effects of the study drug. Complications and side effects from the study drug that are unknown at this time could also occur.

Common side effects (incidence more than 5 out of every 100 individuals, and twice the rate of placebo) associated with the use of quetiapine include:

- Dry mouth

- Drowsiness (somnolence)
- Dizziness
- Sore throat (pharyngitis)
- Weight gain
- Alanine aminotransferase (ALT) increase (liver problems)
- Liver problems (an increase in Alanine aminotransferase or ALT on your lab results)
- Feeling lightheaded when you stand up quickly (postural hypotension)
- Indigestion (dyspepsia)
- Fatigue (extreme tiredness)
- Increased appetite
- Increased blood pressure (hypertension)
- Fast heart rate (tachycardia)
- Vomiting
- Lack of energy

Less common but serious side effects of quetiapine include:

- High blood sugar (hyperglycemia)
- Lipid elevations
- Hypothyroidism
- Malignant Neuroleptic Syndrome (muscle rigidity, fever, or changes in your thinking such as confusion or problems concentrating)
- Seizures
- Diabetes mellitus
- Blurry vision (cataracts)
- Heart problems (QTc prolongation)
- Restless or involuntary muscle movements including tardive dyskinesia. The involuntary movements caused by tardive dyskinesia most commonly appear in the eyes, lips, tongue, and jaw. Although tardive dyskinesia is rare it can be irreversible.

For medications that may pose a serious risk to those taking them, the FDA issues a “black box warning.” The FDA has issued a black box warning for quetiapine which may increase suicidality risk in some adolescents and young adults. However, there is reason to believe this warning arose largely due to co-administration in patients with major depressive disorder who were on antidepressants.

Because it is possible that quetiapine could make your child feel tired, your child should not drive or operate machinery until they know how quetiapine affects their functioning.

Risks of Allergic Reactions

As with any drug, an allergic reaction can occur. Allergic reactions can be mild or serious, and can even result in death in some cases. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think your child is having an allergic reaction, call the study doctor right away. If your child is having trouble breathing, call 911 immediately.

You should notify the study doctor immediately if your child develops a rash, illness or disease that they did not have at the start of the study. If your child becomes pregnant, have an injury or side effect, or

develop an unusual health problem during the study, contact your study doctor, Amy Yule, MD, immediately.

Risks of Drug Interactions
It is possible that taking quetiapine with your child's regular medications or supplements may change how quetiapine works, or how your child's regular medications or supplements work. It is very important that your child tells the study doctor about all prescriptions and over-the-counter medications or supplements your child is taking during the study.

For your child's safety during this study, call their study doctor BEFORE your child takes any:

- **New medications prescribed by their own doctor (for example, antibiotics)**
- **Other medications sold over-the-counter without a prescription**
- **Dietary or herbal supplements**

Your child may be excluded from participating in the study if they are planning to change any of their current medications (psychiatric and/or non-psychiatric) that are known to cause heart problems (QTc prolongation).

Also, your child may be withdrawn from the study if they have to change any of their current medications (psychiatric and/or non-psychiatric) that are known to cause heart problems (QTc prolongation).

Risks of Pregnancy
If your child is female and gets pregnant while in this study, it could be bad for the fetus/baby. Your daughter must use birth control if she has sex with men while in this study. She should also keep using birth control for one week after the study ends. Only some birth control methods work well enough to be safe while your daughter is in this study. These methods are oral contraceptives (the pill), intrauterine devices (IUDs), contraceptive implants under the skin, contraceptive rings or patches or injections, diaphragms with spermicide, and condoms with foam. Your daughter should not be in this study if she has sex with men and cannot use one of these birth control methods.

Risks of Sharing Sensitive Information
Your child will be asked to disclose sensitive, personal information, such as pregnancy or drug use. There is a risk of discomfort in answering these sensitive, personal questions. In addition, it is possible that your child may be inconvenienced by the time required to answer all of our questions.

Risks of Blood Draw
Your child may have a bruise (a black and blue mark) or pain where we take the blood samples. There is also a small risk of feeling lightheaded, fainting, or infection**.** Blood samples will be stored in a locked room only accessible by study staff.

Risks of the EKG
Your child may have a skin reaction to the adhesive used to apply the electrode on their skin.

Risks of Completing Study Questionnaires
Both you and your child will be asked to complete some study questionnaires. There is a risk you/ your

child may feel uncomfortable or anxious while doing some of the computer tests or questionnaires. We hope that you and your child will try to complete all the study questionnaires, but you/your child can skip any questions you all do not want to complete. We will use a study code instead of your child's name on these questionnaires. However, we cannot guarantee absolute confidentiality of this information

There may be unknown risks or discomforts involved.

Potential Benefits

Your child may not benefit from taking part in this research study. It is possible that your child's SUD and/or severe mood symptoms may improve while in the study if you are randomized to receive quetiapine. The results of this study may benefit other people with SUD and co-occurring SMD in the future.

Alternatives

Your child does not need to be in this study to get treatment for their SUD and SMD. There are no medications approved for the treatment of co-occurring SUD and SMD, but there are medications approved to treat the disorders individually. For SUD, the medications ReVia® **(**naltrexone) and Campral™ **(**acamprosate) can reduce the desire to drink alcohol in adults. For bipolar disorder Risperidal® (risperidone), Abilify® (aripiprazole) and Geodon® (ziprasidone) are among the medications approved to treat manic episodes. There are also non-medication treatments available for the management of SUD or SMD, such as cognitive behavioral therapy, group counseling and motivational interviewing. Your child's primary care doctor or psychiatrist may prescribe these drugs for your child and/or refer your child to these therapies without them taking part in this study.

Talk with the study doctor if you have questions about any of these interventions.

Costs

Study funds will pay for study-related items and services. There are no additional costs to you or your child for being in the study. Items and services done only for study purposes will be provided at no cost to your child. They won't be billed to your child's health insurance either. You or your child's health insurance will be billed for all costs that are part of your child's normal medical care. These costs include co-payments and deductibles. You can ask any questions now about insurance coverage for this study or about the research activities paid for by the sponsor. You can also ask the investigator later, using the number on the first page of this form.

Payment

Your child will receive between $10 and $50 for each study visit they complete which will be deposited on a ClinCard. The remuneration schedule is as follows: Visit 1 (screening visit 1): $25; Visit 2 (screening visit 2): $25; Visit 3: $15; Visit 4: $10; Visit 5: $15; Visit 6: $10; Visit 7: $15; Visit 8: $10; Visit 9: $15; Visit 10: $10; Visit 11: $50. In addition, your child will receive a $3.50 at each visit that they bring back their medication in the medication bottle.

You will also receive payment for transportation to Boston Medical Center if you/your child use(s) public transit, or parking in the hospital garage during study visits if you/your child drive(s) to Boston Medical Center. An additional $5 will be deposited on the ClinCard for each visit that you/your child take public transit to and from the hospital. If you/your child park(s) in the hospital garage during a study visit, you/your child will receive a parking coupon.

Compensation will be provided by Boston Medical Center and your child will receive incremental amounts at the end of each completed visit. In order to be paid for taking part in this research study, we will need to collect your child's Social Security Number (SSN) or Individual Taxpayer Identification Number (ITIN). This will be stored in a locked location and will be maintained separately from your child's other study information and documents. If your child does not wish to provide their SSN or ITIN, they can still participate in this study, but we will not be able to pay them.

Confidentiality

We must use information that shows your child's identity to do this research. Information already collected about your child will remain in the study record even if your child later withdraws.

We will store your child's information in ways we think are secure. We will store biological samples taken from your child's body (blood) in a locked room only accessible by study staff. We will store paper files in a locked research office. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC**.** The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you or your child to anyone that is not involved in the research except as we describe below. Even if someone tries to get your child's information or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you or your child from sharing your child's own research information.

We will record information from this study in your child's medical record, such as information related to your child's medical care. A notation that your child is taking part in this research study will be made in their electronic medical record at Boston Medical Center. Information from the research that relates to your child's general medical care may be included in the record (for example: list of allergies, results of standard blood tests done at the hospital labs). Please ask us if you have any questions about what information will be included in your child's medical records. You should know that once information has been put into your child's medical records, it is not covered by the CoC. However, information in your child's medical records is protected in other ways.

If you agree for your child to be in the study and sign this form, we will share information and biological samples that may show your and your child's identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and

Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- People who see your child's medical records.
- Any people who you give us separate permission to share your child's information.

You should know that we are required to report information to a public health or public safety authority, or with specific individuals who may be at risk of harm, if we learn information that could mean harm to you, your child, or others. When state mandatory reporting statues would require us to disclose information, including about child or elder abuse, we will voluntarily disclose that information.

If your child is in immediate danger of hurting themselves at any time in the study, the study team will try to work with you/your child on a plan to keep you safe. Because study staff will be trying to protect your child, it is possible that your information will be shared with others as part of a plan for safety.

We will share research data where we have removed anything that we think would show your child's identity. There still may be a small chance that someone could figure out that the information is about your child. Such sharing includes:
- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Use and Sharing of Your Child's Health Information

The research team has to use and share your child's health information to do this study, including information that may identify you or your child. By agreeing to allow your child to be in this study and signing this form, you are giving us your permission where needed to use and share your child's health information as described in this form.

Health information that might be used or shared during this research includes:
- Information that is in your child's hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
- The health information specifically includes:
  - Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist)
  - Social work communications
  - HIV/AIDS information
  - Sexually transmitted disease information
  - Communicable disease information
  - Alcohol or drug use disorder treatment records

The reasons that your child's health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information. As we explained above, we also have to share any information from you/ your child about: child abuse, elder abuse, or harm to others.
- To protect your child. As we explained above, if your child is in immediate danger of hurting them self, it is possible that your child's information will be shared with others as part of a plan for safety.

The people and groups that may use or share your child's health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Other people within Boston Medical Center and Boston University who may need to access your child's health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- Public health and safety authorities who receive our reports about child abuse, elder abuse, or harm to others.
- Other care providers and public safety authorities who may be involved in helping to protect your child if your child expresses thoughts about hurting them self.

We ask anyone who gets your child's health information from us to protect the privacy of your child's information. However, we cannot control how they may use or share your child's health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your child's health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your child's health information for research. If you do not sign this form, your child cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits for you or your child.
- You have the right to withdraw your permission to use or share your child's health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared

with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, your child cannot continue to be in the study.

- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your child's treatment or payment decisions. If you ask for research information that is not in your child's medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your child's health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG-privacyofficer@bmc.org.

Compensation for Injury

If you think that your child has been injured by being in this study, please let the investigator know right away. Use the phone number on the first page of this form. Your child can get treatment for the injury at Boston Medical Center, or at any healthcare facility you choose. There is no program to provide compensation for the cost of care for research related injury or for other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your child's insurance will be billed for the medical care your child receives for a research injury. You are not giving up any of your legal rights by signing this form.

Re-Contact

We would like to ask your permission to contact you and your child again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes_____No You may contact me and my child again to ask for additional information related to this study

____Yes_____No You may contact me and my child again to let us know about a different research study

Subject's Rights

By giving permission for your child to be in this study, you do not waive any of your or your child's legal rights. Giving permission means that you have been given information about this study and that you agree to have your child participate in the study. Giving permission also means that you agree to allow your child to participate in virtual study visits. You will be given a copy of this form to keep.

If you or your child do not agree for your child to be in this study or if at any time your child withdraws from this study, you or your child will not suffer any penalty or lose any benefits to which you or your child are entitled. Your child's participation is completely up to you and your child. Your decision and your child's decision will not affect your or your child's ability to get health care or payment for your or your child's health care. It will not affect your or your child's enrollment in any health plan or benefits you or your child can get.

During this study, we may find out something that might make you or your child not want to have your child stay in the study. If this happens, we will tell you and your child as soon as possible.

We may decide to have your child stop being in the study even if you and your child want to stay. Some reasons this could happen are if staying in the study may be bad for your child, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions If you have questions or concerns at any time, contact Amy Yule at 617-414-1936. Also call if you need to report an injury to your child during this research Dr. Yule is available 24 hours a day/7 days a week by calling 617-414-1990.

You may also call 617-358-5372 or email medirb@bu.edu if you have questions or concerns. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your child's rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Child Subject: _____
Printed name of subject

By signing this permission form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to allow your child to participate in this research study
- you permit the use and sharing of information that may identify you or your child as described including your child's health information.

_____
Printed name of parent/legal guardian

_____ _____
Signature of parent/legal guardian Date

By signing below, you are indicating that you have read this form, that your questions have been answered, and that you voluntarily agree to participate in this research study.

_____ _____
Signature of child Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named child and to the parent/legal guardian and answered all questions. I believe that they understand what is involved in the study and freely agree to participate.

_____ _____
Signature of person conducting consent discussion Date

To be completed by witness if researcher reads this form to the parent/legal guardian
This permission form was read to and apparently understood by the parent/legal guardian in my presence.

_____
Printed name of witness (a person not otherwise associated with the study)

_____ _____
Signature of witness Date