If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title : Placebo-Controlled trial of Dextromethorphan in Rett Syndrome

Application No . : NA_00064949

Sponsor: U.S. Food and Drug Administration (FDA)
ICTR/NBRU

Principal Investigator: Sakkubai Naidu, MD
Kennedy Krieger Institute
707 N. Broadway, 5th Floor Tower
Baltimore MD 21205
Tel # 443-923-2778
Fax # 443-923-2779

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.
- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.
- The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.

2. Why is this research being done?

This research is being done to study the effects of a drug known as dextromethorphan (DM) to see if it helps patients with Rett Syndrome (RTT). People with Rett syndrome may join.

In RTT there is an increase in the number of brain receptors for a substance known as glutamate. This substance and its increased receptors cause damage to the brain's nerve cells (which are called neurons). We will try to block this harmful over-stimulation of the neurons by use of DM to determine if it will help to improve cognition and behavior, and reduce seizures.
The use of DM in this study is investigational. The word "investigational" means DM is not approved by the U. S. Food and Drug Administration (FDA) for the treatment of RTT. However, the FDA is allowing the use of DM in this study.

How many people will be in this study?
We expect to enroll 60 males and females with RTT, who are one year of age through 9.99 years of age, with a mutation in the MECP2 gene in order to accrue 50 subjects. We will, however, consent 60 participants to allow for those that are not fast metabolizers of DM.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Prior to signing this consent form, you already gave oral consent to join this study so that you may receive and complete a seizure diary one month before admission and fill out a 3-day food diary prior to admission. If eligible, you will then be randomly assigned (by chance, like the flip of a coin) to either the study drug group (DM) or to the placebo group. A placebo is an inactive material that does not contain any active study drug. There is a fifty percent chance of being assigned to each group.

We would ask you to allow your child to stay overnight in the Pediatric Clinical Research Unit (PCRU) at Johns Hopkins ICTR during the first hospital stay before s/he starts the placebo or DM, and the follow-up extended day outpatient visit to the PCRU will be 3 months after s/he starts taking the study drug.
This trial will last for 3 months.

S/he will also be required to have two interim follow up evaluations/tests (described in the "Procedures" section below, to be paid for by this study) done at 2 weeks and 1 month after s/he starts taking the DM or placebo. These evaluations/tests could take place at your local doctor's office or at Johns Hopkins. It is important to have all the required interim follow up evaluations/tests performed at the indicated time

(ie, 2 weeks or 1 month). If there is more than a 2-week delay in obtaining all required interim follow up evaluations/tests, your child will be withdrawn from this study.

In addition, should any test results show an abnormality, they need to be repeated as clinically-indicated tests, which are not paid for by this study.

During the first hospital admission, we will give your child one 2.5mg/kg dose of immediate release DM by mouth to see how the medicine is cleared from his/her body. DM drug levels will be checked thrice by a laboratory test at baseline, 3 hours, and at 12 hours after the DM is given through the use of a heplock. If s/he is unable to clear DM rapidly from the body, s/he would not be able to take part in this study because a safe dose of DM could not be determined. If DM is rapidly cleared from his/her body, then s/he can take part in this study. S/he will be randomized ("like flipping a coin") to the placebo or 5mg/kg/day of DM, which will be given exactly 12 hours apart in two divided doses during the 3 month trial period.

As some drugs may interact with DM, a complete list of medications that your child takes must be given to us before s/he takes part in the study. Also, because certain medications cannot be taken during this study as they may increase DM over the safe dose or interact with DM in a harmful way, you must notify us before you or your physician(s) give any new medication(s) to your child during the 3 month trial period.

This research study may be ongoing at the time your child completes his/her 3-month trial and we may not have completed analysis to determine the effectiveness of DM to suggest that you continue with DM.

PROCEDURES:
If you agree to have your child participate in this study, we request your permission to allow us to perform the followings tests on him/her. Following your written permission for release of information to yourself and/or your physician, we will share some test results from some of the procedures performed below that may have clinical benefit to your child.

1) We will request your permission to access your child's existing medical records.

2) **General Physical Examination and Neurological Evaluation** (takes about one hour) will be done:

- During the first hospital stay before starting the 3-month trial;
  General physical and neurological examinations will be repeated, with ECG and orthostatic blood pressure assessment (due to autonomic dysfunction); (this will take about 10 minutes).
- During the two interim follow up evaluations (required at 2 weeks and 1 month) in our outpatient clinic or with your local physician;
- During the follow up outpatient visit to the PCRU after 3 months of the trial period.

3) **Blood tests** :

During the first hospital stay (a total of about 18cc of blood (about 3.5 tsp) will be drawn (takes about 5 minutes) for:

- Complete Blood Count with differential (CBC/diff) (about 2cc);
- Complete Metabolic Panel (CMP) and Electrolytes (about 2cc);

- Liver Function Test (LFT) (about 1cc);
- A blood test to check how DM is cleared from the body (12 cc or about 2.5 tsp).
- We will obtain about 1 cc of blood to measure cytokines, which are chemicals that cause inflammation. They serve as messengers between cells to regulate various inflammatory responses and the chemical glutamate, in blood. Both these chemicals are present in various parts of the body and we will measure what is released from peripheral blood cells to determine if the study drug modifies the cytokine and glutamate levels.

During the follow up extended day outpatient visit **after 3 months of the trial period (a total of about 12cc of blood (about 2.5 tsp) will be drawn (takes about 5 minutes) for:**

- CBC/diff (about 2cc);
- CMP/Electrolytes (about 2cc);
- LFTs (about 1cc);
- DM level (6cc).
- 1 cc of blood to measure cytokines and glutamate in serum and released from peripheral blood cells to determine if the study drug modifies the cytokine and glutamate levels.

During the two interim evaluations (required at 2 weeks and 1 month during the 3-month study) a total of about 11cc of blood (about 2 tsp) will be drawn (takes about 5 minutes) at 2 weeks and again at 1 month (in our outpatient clinic or with your local physician, to be paid for by this study) to include:

- CBC/diff (about 2cc);
- CMP/Electrolytes (about 2cc);
- LFTs (about 1cc);
- DM level (about 6cc).

No more than three attempts to draw blood at any one time will be made.
No more than 3ml/kg of blood will be taken.

4) **Pregnancy test** *(to be performed on the first day of the first hospital stay, and to be repeated during the follow up extended day outpatient visit after 3 months)*:

If your daughter is able to become pregnant, a small amount of blood will be obtained prior to the test dose of DM (as explained above), so that a pregnancy test can be done. You will be informed about the need and rationale (ie, drug effect) for the pregnancy test.
If you decline the pregnancy test for any reason, your child will be unable to participate in this study.
If the pregnancy test result is found to be positive, your child will be removed from this study.

5) **Electrocardiogram (ECG):** Due to reports of prolonged QTC interval in RTT, an ECG will be performed during the initial hospital stay and again during the follow up extended day outpatient visit after 3 months of the trial period, and also during the 2-week and 1-month interim evaluations (ECG will take about 20 minutes).

6) **Neuropsychological testing:** Will be done during the first hospital stay and again during the follow-up extended day outpatient visit after 3 months of the trial period. A child psychologist will determine cognition, intellect, and adaptive skills by observation, parental interviews and two questionnaires, and administration of cognitively-appropriate psychological testing (this will take about 2 hours).

7) **Neurobehavioral evaluation:** Will be done by a child psychiatrist to assess behavior by observation, parental interviews and questionnaires (this will take about one hour). A parent must complete three questionnaires during the first hospital stay and again during the follow-up extended day outpatient visit after 3 months of the trial period.

8) **Quality of Life Measures:** Will be done to assess the child's physical, emotional, and social well-being from the perspective of a parent or guardian using the Pediatric Quality of Life Inventory (PedsQL version 4). The measures will be obtained during the first hospital stay and again during the follow-up extended day outpatient visit after 3 months of the trial period.

9) **Nutrition Evaluation:** Will be done by the nutritionist to check nutritional status and growth by parental report of dietary history and measurement of body mass, head, height, weight, etc. (this will take about 45 minutes). We will send you a 3-day food record prior to the study to complete and return to us at least 2 weeks prior to the first hospital stay. (We will obtain separate Oral Consent from you requesting you to complete and return the food record prior to admission).

10) **Telephone Follow up Interviews**: Following discharge from the first hospital stay, our research associate or research nurse will phone you (will take about about a half hour or less) at least once a week during the first month, and then at least once a month throughout the 3 month trial period, to find out how your child is doing, to check on the status of the two required interim evaluations (which will take about 1 hour each), and to answer any questions or address any concerns that you may have regarding this study.

11) **Discontinuing/Restarting DM**: If the study drug was discontinued due to severe illness, we would consider restarting the study once your child fully recovers. If the study drug is restarted within 3 months from discontinuation, the evaluations performed during the initial inpatient admission would not be repeated. However, if the time of recovery is more than 3 months, then you will need to re-sign a new Informed Consent form and have your child restart the study.

12) **After-hours Pediatric Resident Coverage**: Will be provided in JHH's ICTR PCRU by the Neill team, which is Johns Hopkins Hospital's standard procedure.

How long will you be in the study?

Your child will be in this study for 3 months. The first hospital visit will be one overnight stay. If eligible for the 3-month drug trial, s/he will be in the study for 3 months. S/he will be required to have two interim evaluations at 2 weeks and again at 1 month. Then, s/he will return to the outpatient clinic for an extended day visit 3 months after starting the study.

4. What are the risks or discomforts of the study?

Dextromethorphan: The potential major risks associated with a high dose of dextromethorphan include: reversible type-1 diabetes, and allergic skin rash. Potential minor risks associated with a high dose of dextromethorphan include lightheadedness, agitation, abnormal eye movements, persistent nausea and/or vomiting, increased liver enzymes, and slurred speech. Dextromethorphan may be associated with mild and infrequent occurrence of dizziness, drowsiness, fatigue, nausea, vomiting, urinary retention, unsteadiness when walking, and abnormal body movements. Withholding dextromethorphan

reverses these symptoms without residual effects. Long-term studies have not been performed with DM, and there may be unknown long-term side effects. Blood electrolytes will be checked for any signs of imbalance that DM may cause, although this has not been reported to date.

Blood draw: There is minimal discomfort from the needle during insertion, with a slight risk of bleeding, bruising, or infection following the blood draw, which can be readily treated. Your child may be fearful or have discomfort during the blood draw, but our staff is well qualified to handle and address these issues.

Pregnancy Testing: For those very few females in their reproductive phase of life and in whom a pregnancy test would be performed, there is the possibility of emotional discomfort to the family if the result is positive.

Blood pressure test: Your child may experience slight discomfort when the cuff is placed around his/her arm.

EKG: Your child may experience slight discomfort during placement of electrodes on the chest and a leg. Rarely, there may be a skin reaction to the electrode paste.

Behavioral and Psychological evaluations: During interviews used to gather information for the questionnaires or scales, you may choose not to answer any question(s) that make you feel uncomfortable or may upset you.

Nutrition Assessment: During the interview with the nutritionist to gather information about your child's diet, food preferences, food allergies, etc. you may choose not to answer any question(s) that make you feel uncomfortable or may upset you. Slight discomfort may occur when measuring your child's body mass, head circumference, weight, and height.

Interview Discomfort: During interviews to obtain information for the intake/clinical questionnaires, you may choose not to answer any question(s) that make you feel uncomfortable or may upset you.

Disruption to work or school schedules: You or your child may undergo disruption to work and/or school schedules when committing the necessary time to undergo the first overnight stay and the extended day outpatient visit, as well as the two required outpatient interim evaluations at 2 weeks and 1month during the 3-month drug trial.

Risk of Disclosure of Information/Loss of Privacy: As all information is kept in locked cabinets or access restricted computerized data, there is minimal risk of disclosure of information or loss of privacy. The blood samples are for research purposes only, and are not for distribution for sale or for selling any products derived from the blood.

Please note that we are expected to publish results of this research study in the medical literature for the general public's knowledge. However, for confidentiality reasons, no identifying information will be given.

5. Are there risks related to pregnancy?

Your child will be excluded from the study if she becomes pregnant, as the possible risks from the study drug to the fetus are unknown. This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There may or may not be a personal benefit to your child from taking part in this study. However, any benefits would only be temporary and occur only while your child is taking the medication. The results of this study may help others in the future.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

No. This research study is sponsored by a research grant. You or your child will not receive any money from us or from the sponsoring agency for participating in this research study.

10. Can you leave the study early?

- You can agree now to allow your child to be in the study and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop your child from getting regular medical care.

11. Why might we take you out of the study early?

Your child may be taken out of the study if:

- Your child is found to be an intermediate or slow metabolizer of DM.
- Staying in the study would be harmful and/or if any drug reactions occur noted in the "Risks" section above, or if any of the blood tests or EKGs are found to be abnormal.
- Your child contracts and does not recover from severe illness within 3 months of starting the study.
- Your child needs treatment not allowed in this study.
- There is more than a 2-week delay in obtaining any of the required interim evaluations/tests.
- Your child's pregnancy test is found to be positive, or your child becomes pregnant during the study period.
- You or your child fails to follow instructions per the study protocol.
- The study is cancelled.
- There may be other reasons that we don't know at this time that may cause us to take your child out of the study.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities**.**

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records ([which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study. If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

- You will be asked to give us a list of other health care providers that you use.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.
- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.
- By signing this form you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

If you are a participant at Kennedy Krieger Institute, you may contact Karen Cox, Vice President and Research Administrator at 443-923-3902.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Sakkubai Naidu at phone # (443) 923-2778. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

If you are taking part at Kennedy Krieger Institute, call Dr. Sakkubai Naidu at phone # (443) 923-2778.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. SakkuBai Naidu, at phone# (443) 923-2778, during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Dr. SakkuBai Naidu at phone# (443) 923-2778 during regular office hours and at phone# (443) 923-9200 after hours and on weekends.

If you are taking part at Kennedy Krieger Institute and you have a medical problem related to your taking part in this study, call Dr. SakkuBai Naidu, at phone# (443) 923-2778. If this doctor is not available, the operator will page the "on call physician."

d. What happens to Data and Biospecimens that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

16. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time
Signature of Parent	(Print Name)	Date/Time
Signature of Legally Authorized Representative (LAR) **For CHILD PARTICIPANT**	(Print Name)	Date/Time
Description of LAR's authority under state or applicable local law to act as surrogate health care decision-maker for child research participant (for example, Legal Guardian, court-ordered representative)		Date/Time
Signature of Parent #2 (required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)	(Print Name)	Date/Time
Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time
Signature of Parent	(Print Name)	Date/Time
Signature of Legally Authorized Representative (LAR) **For CHILD PARTICIPANT**	(Print Name)	Date/Time
Description of LAR's authority under state or applicable local law to act as surrogate health care decision-maker for child research participant (for example, Legal Guardian, court-ordered representative)		Date/Time
Signature of Parent #2 (required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)	(Print Name)	Date/Time
Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

JOHNS HOPKINS
MEDICINE

Insurance and Research Participant Financial Responsibility Information Sheet

Clinical Research Study Title: **Placebo-controlled trial of Dextromethorphan in Rett Syndrome**

Principal Investigator: Sakkubai Naidu, M.B.B.S.

eIRB #: NA_00064949

PRA CIR00011065 Revision #3 Dated: October 5, 2015

The following procedures, tests, drugs or devices are part of this research and will be supplied free of charge by the study:

- General Physical and neurological examinations
- EKG
- CBC with differentials
- Complete Metabolic Panel (CMP) with Electrolytes
- Liver Function Test
- Dextromethorphan PK
- Cytokines from PBMNC
- Glutamate from PBMNC
- Dextromethorphan (DM) blood levels
- Serum Pregnancy test
- Mullen Scales of Early Learning, Vineland Adaptive Behavior scales (VABS)
- Ghuman-Folstein Screen for Social Interaction (SSI), Rett Syndrome Behavioral questionnaire (RSBQ)
- Dextromethorphan or Placebo

You and/or your health insurer will be responsible for all other procedures, tests, drugs or devices that are part of this study such as the following:

- N/A

If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

If you cannot pay the costs that are your responsibility, you may request financial assistance services. If you have received a bill, please contact Patient Financial Services (PFS) Customer Service.

CUSTOMER SERVICE & TOLL FREE PHONE NUMBERS

Toll Free# JHH Inpt./Outpt. 800.757.1700	JHH Inpt./Outpt. 443.997.0100
Toll Free# BMC Inpt./Outpt. 877.361.8702	BMC Inpt./Outpt. 443.997.0200
Toll Free# HCGH Inpt./Outpt. 866.323.4615	HCGH Inpt./Outpt. 443.997.0300