Title: Cannabidivarin (CBDV) vs. Placebo in Children With Autism Spectrum Disorder (ASD)

ID (IRB#): 2017-8538
NCT03202303
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KEY INFORMATION FOR Cannabidivarin (CBDV) vs. Placebo in Children with Autism Spectrum Disorder (ASD).

We are asking you to choose whether or not to volunteer for a research study about using CBDV to treat irritability in children with Autism Spectrum Disorder. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn if CBDV will help reduce irritability in 5-18 years old with Autism Spectrum Disorder. Your participation in this research will last about 12 weeks with additional two weeks for screening and 2 weeks for follow-up, totaling up to 16 weeks.

The purpose of this research is to gather information on the safety and effectiveness of CBDV. CBDV is not approved by the U.S. Food and Drug Administration (FDA). This means that CBDV can only be used in research studies.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

- Your child's behaviors may improve
- You will be reimbursed for your time ($50 for screening and $40 for each subsequent visit)
- Information collected from your participation may help people with Autism in the future
- Participation does not require you to change any of your current treatments

For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

- You may not receive the active drug (may be on placebo)
- Your participation requires you to be evaluated every 2 weeks with 4 in-person on site visits and 5 remote visits, for a total of up to 16 weeks.
- You will have to get some blood draws at your local Quest lab or our on-site Clinical Research Center

For a complete description of risks, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Eric Hollander. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his/her contact information is:
Phone: 718-839-7516
Email: eholland@montefiore.org

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

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DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When the word "you(r)" / "my" / "me" / "I" appears in this consent form, we mean the participant (you or your child); "we" means the research study doctors and research staff.

Introduction

You are being asked to participate in a research study called **Cannabidivarin (CBDV) vs. Placebo in Children with Autism Spectrum Disorder (ASD).** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Eric Hollander, MD. You can reach **Dr. Hollander or one of our study doctors** at:
111 East 210th Street Bronx, NY 10467
Telephone #: **718-839-7516**
Pager #: 917-956-7229
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

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Why is this study being done?

The CDC currently estimates 1 in 68 children have Autism Spectrum Disorder (ASD). Children with ASD have problems with social communication, irritability, repetitive behaviors, impulsivity, temper tantrums, and a high caregiver burden. The only medications approved by the FDA for symptoms of ASD are *aripiprazole* and *risperidone.* Both of these are used to reduce irritability. While they are effective, there are side effects with their long term treatment, including weight gain, metabolic syndrome (i.e., increased risk for heart disease, stroke and/or diabetes), elevation of prolactin (a naturally produced hormone), growth of breast tissue, and movement related side effects. Researchers are developing new medicines to treat irritability in children with ASD that do not have the serious side effects.

This research study will test the value and safety of a new medicine, cannabidivarin (CBDV), to treat autism in children ages 5-18. CBDV is derived from the cannabis plant. Some side effects of CBDV are not known because it has not been extensively tested. During this study, we also want to find out if CBDV is safe to take without causing too many side effects.

CBDV is not approved by the U.S. Food and Drug Administration (FDA). This means that CBDV can only be used in research studies.

Why am I being asked to participate?
You are being asked to participate in this study because you are between the ages of 5 and 18 and have a diagnosis of Autism Spectrum Disorder.

How many people will take part in the research study?
You will be one of about 100 people who will be participating in this study. The study will be conducted at Montefiore Medical Center/Albert Einstein College of Medicine, and one other site.

How long will I take part in this research?
It will take you about 16 weeks to complete this study.
During this time, we will ask you to come to Montefiore Medical Center 4 times for study visits. (Baseline, Week 4, Week 8, and Week 12)

In addition, we will ask you to complete 5 remote visits throughout the study duration as well. Three out of these 5 remote visits will involve assessments performed over the phone as well as a visit to your local QUEST Diagnostic center (Screening, Week 2) The other three remote visits will only involve assessments performed over the phone (Weeks 6, 10, and 14).

What will happen if I participate in the study?
The **Screening Visit (today)** will be performed remotely over the phone. We will do some tests to see if you can take part in this research study. The study doctor will review the results of these tests. If you aren't eligible, the study doctor will tell you why. At this visit we will:

- Review the Informed Consent and discuss Assent (if applicable)
- Ask you about your child's medical history
- Review your child's current medications and treatments.
- If your child is a female able to become pregnant, we will test her urine for pregnancy. Pregnant women cannot take part in this research study.
- Give you some questionnaires to fill out about your child's ASD symptoms.

If you are eligible for the study, we will schedule you for an appointment at your local Quest Lab for some tests. If your lab results are within study parameter, we will contact you and schedule you for an in person visit.

If you are currently taking any medications, you can stay on them. However, you will need to be on the same dose of the medicine(s) for 4 weeks before you are assigned to the CBDV or placebo group.

The next visit, called the **Baseline (**or **randomization) visit**, will take about three hours. At this visit we will:

- Review your child's current medications and treatments.
- Check your child's vital signs, weight and body composition
- Ask you about side effects or health problems since your child's last visit
- Ask your child for a urine sample and test the urine for certain drugs
- Obtain blood sample from participant.
- If your child is a female able to become pregnant, we will perform a pregnancy test.
- Complete the Autism Diagnostic Observational Scale-2 (ADOS-2), an assessment used to help diagnose ASD; during special circumstances (e.g. COVID-19 pandemic) where the ADOS-2 cannot be performed due to site restrictions (e.g. mandatory use of face masks), eligibility can be confirmed using the Autism Diagnostic Interview, Revised (ADI-R)
- Give your child a physical exam, including height, weight, body composition and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Perform an ECG with your child.
- Give your child a brief intelligence test
- Ask you to complete some questionnaires assessing your child's symptoms, dietary intake and family quality of life.
- Perform a Vineland Adaptive Behavior Scale -3 (VABS-3): The VABS measures communication, daily living skills, socialization, motor skills, and maladaptive behavior of individuals with developmental disabilities. The survey will be administered to the subject's caregiver.

At this visit, if you meet all study criteria, we will assign you by chance (like a coin toss) to the CBDV group or the placebo group. You and the study doctor cannot choose your study group. You will have an equal chance of being assigned to the CBDV group or the placebo group.

This research study will compare CBDV to placebo. The placebo looks exactly like CBDV, but contains no medicine. During this study you may get the placebo instead of CBDV. Placebos are used in research studies to see if the results are due to the study drug or due to other reasons.

Visits for weeks 4, 8, and 12 will take about 2 hours on site. At these visits, we will:

- Review any changes in your child's current treatments and medications
- Check your child's vital signs, weight and body composition
- Complete a physical and neurological exam
- Obtain blood samples for safety labs
- Ask you about side effects or health problems since your child's last visit
- Give you some questionnaires to fill out
- Review your dietary diary (For Montefiore site only)
- Collect any unused study drug
- Give you a new supply of study drug
- *ECG at Week 12 only

Visits at weeks 2, 6 and 10 will take place remotely over the phone or computer. Each visit will take approximately 1 hour. At these visits we will:

- Review any changes in your child's current treatments and medications

- Assess for any side effect or adverse events
- Review menstrual and dietary diary for applicable participant
- Assess suicidality with CSSRS and/or safety questions
- Schedule the participant for a visit to your local QUEST Diagnostic for safety labs (Week 2 only)

Visit at Week 14 (follow up) will take place remotely over the phone or computer. This visit will take approximately 2 hours. At this visit we will:

- Review any changes in your child's treatments and medications
- Assess for any side effect or adverse events
- Review menstrual and dietary diary for applicable participant
- Assess suicidality with CSSRS
- Answer a variety of questionnaires with our research psychologist

To obtain the blood sample, we will wipe the skin on your arm with alcohol to clean it. Then, we will insert a small needle into a vein. Three tubes[s] of blood will be drawn at screening and your in-person visits, about 1.5 teaspoons. At remote visit utilizing Quest lab, a lesser amount of blood is needed to check for liver functions. Typically, only 1 tube will be drawn (0.5 tea-spoon).

A description of this clinical trial will be available on 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.

As part of this study we will review your medical records and put the information we collect in our research records.

Will there be audio and/or video recording?

No

Genetic Testing

No. This study will not involve genetic research or genetic testing.

Specimen Banking (Future Use and Storage)

For the samples draw on site here at Montefiore Medical Center, Albert Einstein College of Medicine, we will store your specimens and information about you in a "biobank", which is a library of information and specimens (tissue and blood) from many studies. These specimens and information can be linked to you. In the future, researchers can apply for permission to use the specimens and information for new studies to prevent, diagnose or treat disease, including genetic research. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your specimens and information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy remaining specimens and information but if these were already shared with other researchers, we cannot get them back.

You can choose not to participate in the biobank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS

_____ I consent to have my specimens and information about me used for future research studies.
_____ I do NOT consent to have my specimens and information about me used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

INITIAL YOUR CHOICE BELOW

_____ I consent to be contacted in the future to learn about:
_____ New research protocols that I may wish to join.
_____ General information about research findings.
_____ I do not want to be contacted at all.

Will I be paid for being in this research study?

You will receive a total of $370 for 9 study time points ($50 for today's screening assessments and $40 for the following 8 study time points). If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens (blood) and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

Taking part in this study will not involve added costs to you. All study drugs will be given free of charge by the sponsor, company or the drug makers. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

What will happen if I am injured because I took part in this study?

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the Montefiore Medical Center, a Montefiore doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance.

Albert Einstein College of Medicine and Montefiore Medical Center are not offering to provide you the drug/device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Eric Hollander at (718) 920-4287

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.
- You must take your study drug as instructed, returning any unused study drug (including any empty bottles), at every visit.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- ***Drugs may cause a reaction that, if not treated promptly, could be life-threatening. It is important that you report all symptoms, reactions and other complaints to the research study doctor.***
- If you think you have become pregnant, contact your research study doctor immediately.
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.
- You may carry out all your normal daily activities.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been

asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any times you would not keep my data confidential?
If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

What about the results of pregnancy tests for minors (under age 18)?
Under New York law minors (under age 18) who understand the risks and benefits of available treatments can consent to and obtain sexual and reproductive health care without parental involvement or knowledge. New York State law protects the confidentiality of minors regarding such care. When a minor independently consents to sexual and reproductive health care, the health care provider may not disclose information about it to parents or any other third party without the minor's permission, or unless otherwise required or permitted by law.
We will not tell your parents about the results of your pregnancy test unless you give us permission to tell them.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Questionnaire
You may feel uncomfortable answering questions about you/your children's stress and behavior. You can choose not to answer questions that make you feel uncomfortable.

Blood Draw
Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless "black and blue" may develop. Very rarely, fainting may occur.

Risks of Taking CBDV
To date, 282 people (adult patients and healthy adult volunteers) have taken GWP42006 as a research participant in a GW-sponsored clinical trial. The side effects reported by people who have taken GWP42006 were generally mild to moderate in severity.

In a GW-sponsored trial which looked at convulsions in a type of epilepsy, the following common side effects were reported:

Very common side effects (affected more than 1 person in every 10)

- Diarrhea
- Feeling sleepy.

Common side effects (affected 3 or more people in every 100)

- Feeling nauseous.
- Headache.
- Feeling dizzy.
- Stomach-ache/pain.
- Changes in blood tests that look at how the liver works.
- Changes in anticonvulsant drug levels in the blood.
- Low sodium levels in blood.
- Anemia (low iron levels in blood).
- Back pain.
- Feeling itchy
- Rash.
- Convulsions (only in people who have had convulsions before).

There may be other risks of CBDV that are currently unknown. If you are concerned, please contact your child's trial physician.

As GWP42006 may affect the results of some blood tests, if your child needs a blood test please tell the tester that he/she is taking cannabidivarin as part of a clinical trial.

Risks to Women Who Are or May Become Pregnant
The effect of CBDV on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these unknown risks, women cannot take part in this study if they are:

- Pregnant
- Trying to become pregnant
- Breastfeeding or sharing breast milk

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below. You must use birth control for the duration of the study**.**

Acceptable birth control methods for use in this study are:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

If you miss a period, or think you might be pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you must stop taking the study drug

Taking Study Drug with Other Medications
For your safety during this study, call your study doctor BEFORE you take any:

- New medications prescribed by your doctor
- Other medications sold over-the-counter without a prescription
- Dietary or herbal supplements

Allergic Reaction to Study Drug
Any drug can cause an allergic reaction which could be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you are having trouble breathing, call 911 immediately.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include:

- Direct benefits of participating in the study include:
  - Gold-standard diagnostic assessment for ASD
  - Families will receive feedback on the results of the cognitive and behavioral testing, which may be used to help guide educational and support services for the subject.
- Possible benefits of participating in the study include:
  - Improvement in the core symptoms of ASD (i.e., social communication and/or repetitive behaviors) and/or related symptoms (e.g., irritability).
- Indirect benefits of participating in the study include:
  - Information learned from this study may, in the future, benefit other people with ASD.

What choices do I have other than participating in this study?

You can refuse to participate in the study. You can use current treatments for ASD, including aripiprazole and risperidone and/or treatments/therapies for other ASD-related symptoms (speech/language, occupational, physical therapy). If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers and the Department of Defense may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. You will need to return all unused study drug at this visit. The final study visit will take about three hours. At this visit, we will:

- Review any changes in your child's current treatments and medications
- Check your child's vital signs and weight
- Ask you about side effects or health problems since your last visit
- Ask your child for a urine sample, if female (for a pregnancy test)
- Give you some questionnaires to fill out
- Give your child a physical exam
- Ask your child for a blood sample
- Administer the Vineland Adaptive Behavior Scale –3 (VABS-3)
- Collect any unused study drug

Can the study end my participation early?

We will not let you participate in the study any more if:

- You fail to follow instructions given to you by the research study doctor.
- New information about important medical risks and benefits becomes available.
- You become pregnant.
- For health reasons you need to begin taking medications that are not able to be used while participating in the study.
- You develop medical problems that affect your participation in the study.
- You have a negative reaction to the study treatment or worsening of symptoms.
- Administrative reasons.
- If the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not my child will participate in a research study. I have had the opportunity to ask questions and have had them answered to my (my child's) satisfaction. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I authorize the use and disclosure of my child's health information to the parties listed in the authorization section of this consent for the purposes described. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Please initial one selection below:

_____My child appears to understand the research to the best of his or her ability and has agreed to participate.

_____My child is not capable of understanding the information in the assent form.

Parent/Legal Guardian:

_____
Printed Name of Parent/ Legal Guardian

_____
Relation to Subject Subject Name (Printed)

CONSENT TO PARTICIPATE (Parental Permission)

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant (not applicable for participants under age 13)	Date	Time
Printed Name of Parent or Guardian (when applicable)	Signature of Parent or Guardian (when applicable)	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time

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ASSENT FORM – Ages 7-17

Does Cannabidivarin (CBDV) help Children with Autism Spectrum Disorder (ASD)?

Cannabidivarin (CBDV) vs. Placebo in Children with Autism Spectrum Disorder (ASD)

What is this about?
I want to tell you about a research study we are doing. A research study is a way to learn information about something. We would like to find out whether a new medicine from a plant can help children with ASD feel better.

We will get information for the study from 100 children like you**.** You are being asked to join the study because you have ASD and because you are between 5-18 years old. The researcher in charge of this project is called the "Principal Investigator." His name is Dr. Hollander.

What do you want me to do for the study?
If you agree to be part of this study, you will be asked to take a medicine every day, and to come to clinic a total of four times so that we can ask you some questions, like how you are feeling. We will also measure your height, weight and blood pressure at these visits, do an exam with you, and if you are female, we will ask you for a urine sample. We will also need to take a little blood from your arm. Today, you will also get to play some games with one of the doctors.

In addition, we will also ask you to visit a local QUEST diagnostic lab three times in between your in person visits to take a little more blood from your arm.

Will it hurt to be in the study?
Taking blood from your arm or finger may hurt a little. Also, you may not like some of the games that you play with the doctor. If you don't like any of them, please tell him/her. During the study, you may not feel very hungry or you may feel tired.

Will the study help me in any way?
We do not know if being in the study will help you. But we may learn something that will help other children with ASD someday.

Do I have to be in the study?
You do not have to join this study. It is up to you. No one will be mad at you if you say no to the study. You can say okay now, and you can change your mind later. All you have to do is tell us.

Do you have any questions?
You can ask any questions that you have about this study. If you have a question later that you did not think of now, you can call me at 718-920-2909, or ask me next time.

We will keep your information private.
The only people who will know about what you tell us in this study is the people who work on the study and your parents. We will not tell anyone else what you say or do in the study, including your teachers.

If you are willing to be part of the study, please sign here. We will give you a copy to keep.

ASSENT TO PARTICIPATE

This research study has been explained to me. I agree to take part in this study. I have had a chance to ask questions. If I have more questions, I can ask the doctor.

Printed name of participant	Signature of participant	Date

Printed name of the person conducting the assent discussion	Signature	Date