COVER PAGE

STUDY TITLE:

THE ROLE OF ANTIDEPRESSANTS OR ANTIPSYCHOTICS IN PREVENTING PSYCHOSIS: FLUOXETINE VS ARIPIPRAZOLE COMPARATIVE TRIAL (FACT)

CLINICALTRIALS.GOV PRS RECORD - NCT02357849

VERSION DATE: 03/09/16

THE ZUCKER HILLSIDE HOSPITAL
A DIVISION OF NORTHWELL HEALTH

INFORMED CONSENT FOR RESEARCH

Title: The Role of Antidepressants or Antipsychotics in Preventing Psychosis: Fluoxetine vs Aripiprazole Comparative Trial (FACT)

Principal Investigator: Christoph U. Correll, M.D.

Sponsor: National Institute of Mental Health (NIMH)

Please read this document carefully before signing.

NOTE: This consent form is written from the point of view of a research subject. If consent will be obtained from the parent/legal guardian of a minor, the words "you" and "your" should be read as "your child".

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 the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. 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 be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- You will be told of any new findings that may change your decision to participate.
- Neither medication is specifically indicated in adolescents for the symptoms for which they are prescribed in this study. However, both medications are widely used for a range of disorders in children and adolescents, and both have been used successfully in other studies at the Zucker Hillside Hospital, including in adolescents with the same conditions as you have and that are the focus of this project.

Financial Disclosure

Sometimes a study doctor has a financial interest that could be affected by the results of the study. Dr. Correll, one of the doctors involved in this study, receives financial support from Alkermes, Intracellular Therapies, Janssen/Johnson & Johnson, Lundbeck, Takeda Pfizer, Sunovion and Otsuka. Aripiprazole, one of the medications that is involved in this study is made/marketed by Otsuka and Lundbeck. The money this study doctor receives from these companies is for work as a consultant, lecturer and/or advisor. This is separate from the sponsor's support of this study.

Why is this research being done?

The purpose of this study is to compare the usefulness and effects (good and bad) of two medications, aripiprazole and fluoxetine, in the treatment of levels of suspiciousness, unusual thoughts and sensory experiences, odd behavior, social isolation, and poor school/work functioning in children, adolescents and young adults. You are being asked to participate in this study because you have at least one of these

symptoms at a moderate level of severity, but you do not have a major psychotic disorder diagnosis. No single medication has been demonstrated to be best for this group of symptoms.

How many people will be in this study?
We are planning to enroll 48 participants in this study.

How long will you be in this study?
If you choose to participate, you will be in this study for approximately 25 weeks (about 6 months).

What will happen if I join this study?
This study consists of two parts.

- Part one is the screening evaluation (1 visit)
- Part two is the study treatment and evaluation phase (24 weeks long – 11 visits)

Screening Phase (1 visit)
If you agree to take part in the study, you will first receive a screening evaluation to see if you are eligible to participate in the medication treatment part of the study. This visit will take approximately 3 hours. During the screening visit, you will be interviewed with questions about thoughts and feelings to see which diagnoses you and the level of some of the symptoms you are experiencing. At the same time your parent or legal will also be asked similar questions.

You will undergo a physical exam, including measurement of your height, weight, and vital signs to see if you have any health problems. A urine sample will be collected to test for amphetamines, cannabis and cocaine. If you are a female is of childbearing age, your urine sample will also be used to test for pregnancy. Approximately 1 tablespoon (15mls) of blood will be drawn for laboratory testing.

Females of childbearing age are required to take a pregnancy test to determine if they are pregnant. If you are pregnant, you will not be able to participate in the study. In general, a urine pregnancy test will be performed, unless you are unable to provide urine. If this is the case, a blood sample will be obtained to test for pregnancy.

Your treatment history will be carefully evaluated by the study doctor to determine if you are eligible for the study.

Treatment & Evaluation Phase (11 office visits over 24 weeks)
After the screening visit, participants who are eligible will continue with the second part of the study. During this 24-week period, there will be 11 office visits. These consist of 5 visits (baseline, 4, 8, 12 and 24) which will last approximately 2 hours and 6 shorter visits (1, 2, 3, 6, 16, and 20) that will last approximately 1 hour.

At the baseline visit, participants will be randomized into one of two groups. This means that you will be assigned to a group by chance (like flipping a coin or drawing numbers from a hat). The two groups are –

- Treatment with Fluoxetine
- Treatment with Aripiprazole

You and the study doctor will not know which group you have been randomly assigned to.

In order to know whether the study treatments are effective in improving health, it is important to compare them without knowing which medication you are taking. At the baseline visit and at each visit thereafter, you

will be given either Fluoxetine or Aripiprazole in identically looking capsules. Every participant will receive an active medication (Fluoxetine or Aripiprazole)

At each office visit, we will record your weight and vital signs, and the study doctor will ask about your symptoms and any side effects. The study doctor will evaluate you and decide if the dose of your medication should be changed and whether adjustments should be made to other medications that you had been taking. Some participants will require additional medications in order to manage side effects. For example, certain medications may be prescribed to treat sleeplessness (insomnia), restlessness or anxiety, should these symptoms arise. You will be given a medication supply to last until the next office visit.

A urine drug test and pregnancy test for females of child bearing age will be completed at baseline and every 4 weeks for the first 3 months, and then at the end of the study.

Medications

Fluoxetine is approved by the Food and Drug Administration (FDA) for the treatment of depression, obsessive-compulsive disorder (OCD), panic disorder in adults; and depression, anxiety and OCD in children and adolescents.

Aripiprazole is approved by the FDA for the treatment of schizophrenia, bipolar disorder and major depressive disorder in adults; and in children and adolescents with schizophrenia (ages 13-17), bipolar disorder (ages 10-17), and for the treatment of irritability associated with autistic disorder (ages 6-17).

Neither medication is specifically approved in adolescents for the symptoms for which they are being used in this study. Thus, in this study the drugs are considered investigational.

Birth Control

The drugs in this study may affect a baby, before or after the baby is born. As a result, women should not be in this study if they are:

- Pregnant
- Breast-feeding, or
- Trying to become pregnant

If you are a female of childbearing age, you should use abstain from sex or use birth control for the entire time you are in the study. Hormonal methods (birth control pill, etc.), double-barrier methods (condoms with spermicidal, sponge with spermicidal, or diaphragm with spermicidal), or not having sex may be used. Your doctor will discuss these with you.

As per NYS law, the results of your pregnancy test will not be shared with your parents without your permission.

Schedule of Study Visits

	Screening	Week 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12	Week 16	Week 20	Week 24
Diagnostic interview and SOPS rating	√											
Study doctor visit	√	√	√	√	√	√	√	√	√	√	√	√
Symptom ratings	√	√	√	√	√	√	√	√	√	√	√	√
Blood draws	√	√				√		√	√			√
Pregnancy test (urine) (females)												
Toxicology test (urine)	√	√				√		√	√			√

Medication Schedule

	Week 0/1	Week 1/2	Week 2/3	Week 4- Week 24
Visit number	Baseline	Visit #1	Visit #2	Visits 3-10
	Fixed	Fixed	Fixed	Flexible Dosing
Fluoxetine	10mg*	10 mg*	20 mg*	10 mg – 60 mg*
Aripiprazole	2 mg*	5 mg*	10 mg*	5 mg – 30 mg*

*Indicates daily dose

After your participation in the study is complete, you will resume medical care with your original physician. Your personal doctor will receive a letter that will include the details of your study medication dose, study length, benefits, side effects and results of laboratory work. This letter will help with the transition of your care from the research unit to the personal clinician's office. Therefore, continuation of any of the study medications provided during the study will be decided by you, your parent/legal guardian (if applicable), and your personal doctor/clinician.

Optional Collection, Research and Storage of Genetic Material

You are eligible to participate in the optional genetic research study, since you are in the main study. In an effort to find out the reasons people have good and bad effects from the medications that you are taking in this study and to better understand the underlying illness that prompted the use of these medications, we are requesting that you allow us to obtain two blood samples of your blood (16ml each either at the baseline visit or at any other visit throughout the study) to look at your genes and DNA.

There is no direct benefit to you for participating in the optional genetic research study. However, this study may help us learn where a certain gene within DNA is located, identify changes in this gene that may help us learn more about it and may give us information about the disease(s) linked to this. This may lead to better treatment and management of the disease. There may also be other benefits to society that we do not yet know.

In order to protect your confidentiality, we will not share the results of the genetic testing with you, your family members, or any their party. This includes insurance companies and your employer.

We ask for your permission to collect two blood samples of 16 ml each for genetic analysis. You do not have to consent to the genetic portion of this research study in order to participate in the main study.

Please indicate your decision for this optional portion of the study -

_____ I agree to provide one blood sample used to obtain DNA (genetic material).

_____ I do not agree to provide one blood sample used to obtain DNA (genetic material).

Your samples will only be used for research about medication related effects and the illnesses prompting their use. The samples collected will be stored in locked freezers. The samples will be inventoried and stored by codes defined by the researchers involved in this project. Samples will be stored for the period of this study and for an additional 10 years, unless you give us permission to use the de-identified samples indefinitely (see below) to be able to answer future research questions. Other researchers may be interested in using your samples to pursue their own individual research projects.

Since you have control over the use of your samples, we ask your permission in considering their use in other studies. You do not have to consent to the future use of your samples in order to participate in the main study.

I give my permission to use my sample in future studies under the following conditions (to be initialed by subject):

_____ Future studies can be completed without contacting me if all identifying information is removed so that the sample cannot be identified as mine.

_____ I wish to be re-contacted if future studies with this sample are considered. After the project has been explained to me, I will then decide if I want my sample to be included in the project.

_____ Under no circumstances shall the sample be used for future studies.

What are the risks or discomforts of the study?
Risks or discomforts associated with participation in this study may include –

Risks associated with the medications used in the study

Likely	**Medication A:** drowsiness or trouble sleeping, dizziness when standing up, blurred vision, constipation or upset stomach, increased appetite, weight gain, headache, dry mouth, rash, cough, runny nose, nervousness, and easier sun burning.

	Medication B: headache, stomach upset, increased energy and activity, less sexual interest, sleeping too much or too little.
Less Likely	**Medication A**: stiffness, shaking, twitching, restlessness, sore throat, problems breathing or swallowing
	Medication B: nausea, diarrhea, lack of appetite or weight gain, restlessness.
Very Rare	**Medication A:** elevated blood sugars, diabetes, tardive dyskinesia (involuntary twitching of muscles, tongue, limbs, etc. – that can be irreversible), neuroleptic malignant syndrome (high fever >102° F without clear infection, unstable blood pressure or pulse, inability to pass urine, unusual confusion, seizure/convulsions, body temperature regulation problems, impairment of thinking or movements, agitation and, very rarely, death), heart and blood vessel disease, joint disease, potential for increased suicidal thinking and behavior.
	Medication B: increased suicidal thinking and behavior.

Potential for worsening of psychiatric symptoms: Signs and symptoms of worsening psychiatric status might include new or worsening difficulties with –

- sleep,
- attention or concentration,
- restlessness,
- feeling or acting aggressive, dangerously or strange,
- feeling overly happy without any reason,
- feeling depressed for no apparent reason,
- feeling hopeless or suicidal,
- wanting to hurt oneself or wanting to hurt someone else,
- feeling distrustful of others,
- seeing, hearing, feeling, smelling or tasting things that are unusual or that others can't recognize.

To minimize the potential risk of worsening psychiatric symptoms, you will be carefully monitored by the study doctor.

If your symptoms worsen, you may be withdrawn from the study to ensure appropriate medical care. Since clinical worsening may be related to issues beyond antipsychotic and antidepressant treatment (for example, recent stress or trauma, development of a new psychiatric condition, or failure to take medications), a decline in functioning will not necessarily lead to discontinuation of the study medication or withdrawal from the study, but will lead to a thorough clinical review of the case by the study team. The study team will then decide if you should continue in the study or possibly change your clinical treatment (for example, you will be seen more frequently) (Note: as these are clinically indicated visits (and not research visits), you will not receive extra reimbursement for them). The Principal Investigator has the ability to withdraw you from the study for any reasons felt appropriate.

Note for Adult Participants and Parents/Legal Guardians: If psychiatric symptoms worsen, you will

- need to report this immediately to the study doctor, and/or
- seek medical assessment as soon as symptoms are noted (if applicable) rather than waiting for the next scheduled visit.

Blood draw: There are no major risks of having blood drawn. Risks of a blood draw include pain at the site of the need. Bruising can sometimes occur. In rare cases, fainting or infection can occur. These risks will be reduced by carefully cleaning your skin before introducing the needle, by using the smallest possible needle to take the blood, and by applying pressure to the site after the blood has been taken.

Self-Reports: When answering questions or completing questionnaires, you may get tired, bored, or anxious. If you feel tired or anxious, you can take a break from answering the questions or choose not to answer the question. You do not have to complete any question that you do not want to answer. All of these uncomfortable experiences are expected to be mild and last only for brief period of time.

Risks of discomfort associated with identifying suspected abuse or neglect or danger to self or others:
Any information about suspected abuse or neglect that is revealed during the course of assessment or treatment will be reported to child protective services according to mandatory reporting guidelines. If your safety or that of those around you is in question you may be hospitalized involuntarily.

Unknown Side Effects
As with any drug, there might be side effects that are unknown at this time. You will be monitored for side effects. You should report any unusual events to the study staff.

Risks to Women of Childbearing Potential and Pregnant Women
We do not know the effects of the study medication on fertility or a fetus. For this reason, if you believe you are pregnant or have a chance of becoming pregnant, you should not participate in this study. A urine pregnancy test will be performed prior to the start of study procedures. If you are unable to provide a urine sample, a blood sample will be collected to test for pregnancy. Pregnancy tests will be performed at week 0, 4, 8, 12 and 24 of the study. If you are pregnant, you will not be allowed to participate in the study.

If you do participate in this study, you must either abstain from sexual activity or use a medically recognized form of birth control for one month before entering the study, while participating in the study, and for at least one cycle after stopping the study. If you become pregnant during the study, you will be immediately withdrawn from the study and followed through the outcome of your pregnancy.

The side effects of this of this experimental procedure on newborns are also not known; therefore, if you are currently breastfeeding, you cannot participate in this study.

Your parent/legal guardian will not be given the results of your pregnancy test without your persmission.

Are there benefits to being in the study?
The possible benefits you may experience from the procedures described in this study include possible benefits from either of the study medications on the symptoms that are the target of the interventions. Additional benefits include access to intensive monitoring of efficacy and side effects (beyond what can be achieved in a standard clinical setting) and medication treatment. Data obtained from the intensive monitoring will improve both the caregiver and treatment provider's ability to assess ongoing risks and benefits associated with continued treatment. The results of this study may help others in the future.

If you do not want to take part in this research study, what are your other choices?
You do not need to participate in this study to receive treatment with antipsychotic or antidepressant medication for your condition. You may decide to not participate in the study and receive standard clinical care. You can receive fluoxetine or aripiprazole without participating in this study.

Are there any costs for being in this research study?

You will not be billed for study related procedures and treatments. The costs for aripiprazole and fluoxetine will be covered by the study sponsor. The cost for all other medications you might be taking will continue to be covered by your insurance company.

Will you receive any payments for participating in this research study?
You may receive up to $300 in reimbursement for compensation of your time and effort.

You will be paid $30 for the screening visit and visits on weeks 0, 4, 8, 12, and 24 for a total of $180; and $20 for visits on weeks 1, 2, 3, 6, 16, and 20 for a total of $120.

If you stop the study before the last study visit or miss reimbursable study visits, you will only be reimbursed for the study visits that you attended. If you withdraw before the study is completed, you will be paid for your participation up to that time.

Compensation will be provided as check or cash after each reimbursable study visit with instructions that it is intended to support the entire family's expenses associated with the study visit. Additionally, participants will be provided with a voucher at each scheduled visit to cover the cost of parking and/or public transit. After your blood draws, a light, healthy meal or meal voucher will be given to you. If you are given a meal voucher, you will be guided to the cafeteria where you will be able to pay at the cashier with the voucher instead of using money.

If the total payment you receive from Northwell Health, during this year, is equal to $600 or more, the payment is required to be reported to IRS. Although this study does not pay $600, if you participate in other Northwell Health studies, it is possible your payment could end up totaling $600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return.

If the research produces marketable products, will you receive any payment?
If this research produces a marketable product, there are no plans for you to receive any money.

What happens if you am injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed from the Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance and/or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at the NorthwellHealth. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by an investigator, study sponsor or the IRB.

Reasons for withdrawal may include:

- failure to follow instructions,

- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new information will be collected. Any remaining samples you have contributed will be discarded at the point of your withdrawal.

If you leave the study early, the Zucker Hillside Hospital may use your health information that it already has if the information is needed for this study or any follow-up activities**.** Your data will be treated confidentially in the same way if you complete the study or discontinue early. In addition, gradual withdrawal may be required for safety considerations by a 50% reduction in dosage for aripiprazole and fluoxetine.

How will your privacy and confidentiality be protected?

If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record and ask other health care providers to give us information about your health status and healthcare. You will be asked to give us a list of other health care providers that you use. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside of the Northwell Health, except as detailed below.

Investigators will share the results of your study tests and procedures with:

- study sponsor, which is the National Institute of Mental Health or its agents,
- data safety monitoring board,
- clinical staff not involved in the study who may be involved in your treatment, health insurers or payers

In addition, your records may be reviewed in order to meet federal or state research regulations. Reviewers may include representatives from government agencies, i.e. [the Food and Drug Administration, NIH (National Institutes of Health), NIMH (National Institute of Mental Health, etc.], and the NS-LIJHS Institutional Review Board (IRB – the committee that reviews research at this institution). If your research record is reviewed by any of these groups, they may also need to see your entire medical record.

Please be aware that once private information is disclosed, it is subject to re-disclosure by the recipient and can no longer be considered protected by the federal law.

If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, or for any questions related to your health information, you may contact the Research Privacy Officer at 516-321-2100.

If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Christoph U. Correll, M.D.
The Zucker Hillside Hospital,
Department of Psychiatry Research
75-59 263rd Street
Glen Oaks, NY 11004

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

The information that is collected for research will be analyzed for many years and it is not possible to know how long this analysis and follow-up will take. Therefore, you are allowing access to this information indefinitely.

Data from this research may be used in medical publications or presentations. The information will be de-identified so that individual subjects cannot be recognized and the information will no longer be considered Protected Health Information (PHI).

What if there is a Certificate of Confidentiality for this study?
To help us protect your privacy, we have applied for a Certificate of Confidentiality from the US Department of Health and Human Services (DHHS). The Certificate of Confidentiality will mean that the researchers cannot be forced to identify you, even under a court subpoena. The Certificate does not mean the Secretary of DHHS approves or disapproves of the project. It adds special protection for the research information about you. You should know, however, that researchers may provide information to appropriate individuals or agencies if harm to you, harm to others, or child abuse becomes a concern. In addition the federal agency funding this research may see your information if it audits us.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. However, if an insurer, employer, or other person learns about your participation and obtains your consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Who do you contact if you have questions or concerns?
If you have any questions regarding the project, side effects or research-related injury call **Dr. Christoph Correll at 718-470-4812**. If you need emergency care, you may call the Emergency Department at 718-470-7500 or dial 911. For questions regarding your rights as a research subject, you may call the Office of the Institutional Review Board (the committee that oversees research at this Institution) at (516) 321-2100. A copy of this signed consent form will be given to you.

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

RESEARCH REVIEW QUESTIONNAIRE TO FOLLOW

RESEARCH REVIEW QUESTIONNAIRE

Please answer the following questions after reviewing the consent form for this study. The researchers doing this study want to be sure that you know what is involved in being in this research study. This questionnaire will help them make that decision. You may ask questions of the researcher and review the consent form again at any time.

I am being asked to be in a research study.	True	False
This study involves the use of a drug not approved by the FDA for adolescents to treat the symptoms for which they are prescribed in this study.	True	False
I have to participate in this research study to receive care.	True	False
I and my doctor will know which study medication I am taking	True	False
I can withdraw from participating in this study at any time.	True	False
There are no risks to me from participation in this study.	True	False
I am guaranteed to feel better from being in this study.		

_____
Printed Name of Subject

_____ _____
Signature of Subject/LAR/ Date

_____ _____
Investigator's Signature Date

THE REMAINDER OF THIS PAGE IS LEFT BLANK INTENTIONALLY

Summation of Signatures

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

If you are consenting for yourself (≥ 18 years old)

_____	_____	_____
Subject's Printed Name	Subject's Signature	Date
_____	_____	_____
Witness's Printed Name (Preferably someone not connected with the study)	Witness's Signature	Date

_____

OR

If you are consenting as the Parent or Legal Guardian of a minor:

_____
Subject's name

_____	_____	_____
Parent's/Legal Guardian's Printed Name	Parent's/Legal Guardian's Signature	Date
_____	_____	_____
Witness's Printed Name (Preferably someone not connected with the study)	Witness's Signature	Date

Physician's Statement

In addition to advising the above subject or the subject's parent/legal guardian of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study, and to answer any further questions related to it.

_____	_____	_____
Physician's Printed Name	Physician's Signature	Date

ASSENT BY MINOR SUBJECTS LESS THAN EIGHTEEN YEARS OF AGE

I have been asked to join this research study. I have the right to find out what will or might happen to me if I am in the study. I have the right to tell my parent(s)/guardian and the doctor whether I do or do not want to be in this study.

My parent(s)/guardian will also be asked to give permission for me to be in this study.

_____ and my parent(s)/guardian have explained what I will have to do in the study.

_____ and my parent(s)/guardian have also explained any discomforts, risks and inconveniences I may experience if I am in the study.

I have been told that I will be given at least five urine drug tests. If the drug test is positive, then one of the study doctors will meet with my parents and tell us the results.

I agree that I need to avoid using any alcohol, including beer and wine, while in this study, as it could make me sick and cause serious side effects.

If I am female, I have been told that I will be asked to discuss sexual activity and birth control in private and my parents will only be involved in the discussion if I want them to be there.

If I am a female, I have been told that I will have pregnancy testing if I am able to have a child and the results will be kept private and not shared with my parents without my permission. I have been told that I need to remain pregnancy free throughout the study.

I have asked any questions I had, and all my questions have been answered (to be initialed by subject):

_____ I agree to be in this study.

_____ I do not want to be in this study.

_____
Subject's age

_____	_____	_____

Subject's Printed Name Subject's Signature Date

Witness's Printed Name Witness's Signature Date
(Preferably someone not connected with the study)

All procedures, risks and discomforts have been explained to the subject.

Physician's Printed Name Physician's Signature Date