SAMPLE CONSENT FOR TADS

"Treatment for Adolescents with Depression Study"

PURPOSE OF STUDY

You are being asked to allow your teenager to be in a research study funded by the National Institute of Mental Health and coordinated by Duke University Medical Center. Your teenager may be eligible for this study because he or she is depressed and currently requires treatment for depression. Approximately 432 teenagers (between the ages of 12 and 17) will take part in this study at ten sites in the United States.

The purpose of this study is to compare how well different treatments work in teenagers diagnosed with major depressive disorder. A second purpose of this study is to see which treatment(s) produce the most immediate and long-lasting benefit.

YOUR RIGHTS

It is important for you to know:

1. This study is strictly voluntary. No teenager will be required to be in this study, even if his or her parent wishes it.
2. At any time during the course of this study, you or your teenager can change your mind, stop your participation, and receive appropriate treatment elsewhere.
3. If your teenager or you decide not to be in this study, this decision will not affect his or her routine medical care at [facility].
4. You and your teenager will be informed of any changes in the way the study is conducted and any new risks that your teenager may be exposed to, if any should occur. If necessary, you may be asked to sign a new *Informed Consent*.
5. Your teenager and you will be informed of any new information learned during the course of this study that could cause you to stop participating in this study. If it is in your teenager's best interest, your doctor may decide to withdraw him or her from the study without your consent.

STUDY PROCEDURES

Your teenager will first receive a complete diagnostic assessment to determine if he or she is eligible to participate in this study. This assessment will take approximately two half days and will involve interviews with you and your teenager, questionnaires for you and your teenager, an achievement test for your teenager, and a brief physical exam for your teenager. If your teenager is female, she will be asked to give a sample of blood (about one teaspoon) [or urine, depending on site] to determine if she is pregnant. You and your teenager will be told the results of the pregnancy test [include depending on local requirements]. Pregnancy will disqualify your teenager from being in this study.

If your teenager is eligible and you both agree to participate, your teenager will be randomly assigned (meaning assigned by chance, like flipping a coin) to one of four (4) treatment groups. Neither you nor your doctor will be able to decide which treatment your teenager receives; the computer will decide it.

Two of the four treatment groups will receive active (real) medication. The medication used in this study is called fluoxetine, and is more commonly known as Prozac. Research has shown that medications like fluoxetine help depression in young persons. Fluoxetine has been approved by the Food and Drug Administration for use in the treatment of adult depression and is under study for children and teenagers.

One of the two fluoxetine groups will receive only fluoxetine and is referred to as the Fluoxetine alone group. The other group will receive fluoxetine plus Cognitive Behavioral Therapy (CBT) and is referred to as the Combined Fluoxetine and CBT group. CBT is a talking therapy that will teach you and your teenager new skills to cope better with his or her depression. Specific topics include education about depression and the causes of depression, setting goals, monitoring mood, increasing pleasant activities, social problem-solving, correcting negative thinking, negotiation, compromise and assertiveness. CBT sessions will also help with resolving disagreements as they affect your family.

The third treatment group will receive only CBT, without any medication. It is referred to as the CBT alone group.

The fourth treatment group will receive no medication and no CBT. However, those in this group will take a "fake" pill that has been made to look like fluoxetine so that neither the teenager, the parents, nor the doctors will know who is getting real medication and who is not. The group is referred to as the Placebo alone group.

Again, the four possible groups are:

1. Fluoxetine (Prozac) alone
2. Combination of fluoxetine and CBT
3. CBT alone
4. Placebo alone

In groups one and four (Fluoxetine alone and Placebo alone), neither the study doctor nor you will know which medication (i.e., real Prozac or Placebo) your teenager is receiving. However, if it becomes necessary for safety reasons, the study doctor will be able to find out which medicine your teenager has been taking.

The treatment part of this study will be conducted in (3) three stages and may last 36 weeks (9 months), depending on your teenager's response to treatment. A fourth follow-up stage will last one year.

Stage I will last 12-weeks and will compare each of the four treatment groups listed above. Depending on which treatment group your teenager is randomly assigned to, he or she will come to the clinic between 6-12 times during Stage I of the study. If your teenager's depression has worsened or not improved enough during Stage I, the study doctor will talk to you both about other treatment possibilities.

The schedule of visits during Stage I is:

1. If your teenager is assigned to one of the medicine groups (either active medication or "pill placebo"), you and your teenager will visit the study doctor 6 times during Stage I. Each visit should take about thirty minutes. During these visits, the study doctor will ask your teenager about both benefits and side effects before deciding if your teenager needs more of the medicine. As long as your teenager remains depressed, clinic staff will call you to see how he or she is doing during the weeks that you do not see the doctor. At the end of 12 weeks you and your teenager will find out which medication your teen has received.
2. If your teenager is assigned to the CBT alone group, he or she will visit the psychologist during Stage I. There will be approximately 12 CBT sessions, depending on your's and your teen's need. As a parent, you will attend some sessions, sometimes with your teenager and sometimes alone with the psychologist. Each visit should last one to two hours.
3. If your teenager is assigned to the combination of medication and CBT group, he or she will meet six times with the study doctor (for medication) and about 12 times with the psychologist (for CBT) during Stage I. As a parent, you will also attend some of these visits with your teen and sometimes alone with the psychologist. To minimize the time and trouble to you, these visits will be coordinated back-to-back in the same location.

If your teenager is assigned to the "pill placebo" group and he or she has not improved over the course of Stage I, your teenager will be eligible to receive 12-weeks of the active medicine (fluoxetine) or therapy (CBT) or both, depending on your preference.

Stage II lasts six weeks and is for those teenagers who have responded well during the first 12-weeks of treatment. In Stage II of the study, your teenager's original treatment will be continued and he or she will come to the clinic between 2-6 times during Stage II of the study. If your teenager's depression has worsened or not improved enough during Stage I,

the study doctor will talk to you and your teenager about other treatment alternatives.

Stage III lasts 18 weeks, about four months. During Stage III, if your teenager has continued to respond well, he or she will return every six weeks to receive treatment and to monitor progress. If he or she received fluoxetine, he or she will see the doctor who gave the medicine; if she or he received CBT, she or he will see the CBT therapist. If he or she was in the combined group, he or she will see both the CBT therapist and the medication doctor.

At the end of Stage III, your teenager's treatment in this study will end. Your doctor will talk with you and your teenager about the progress your teenager has made and give you recommendations for further treatment and appropriate referrals.

Stage IV lasts one year. During Stage IV, you and your teenager will return every three months for assessments only. Stage IV will help us understand the long-term benefits of the treatments.

By agreeing to be in this study, you also agree to complete all assessment visits even if your teen is no longer receiving treatment from TADS staff. These visits, which are necessary to know how well the treatments work, may or may not be on the same day as a treatment visit.

ASSESSMENTS

There are two kinds of assessment visits, minor and full. Minor assessment visits will take about an hour and will usually happen on the same day as a treatment visit. Full assessment visits will take 3-4 hours and may or may not happen the same day as a treatment visit.

There are five minor and six full assessments over twenty months (Stages I-IV). During Stage I, II and III, an assessment visit will occur every six weeks, with full and minor assessments alternating. Full assessments will occur right before treatment starts and at weeks 12, 24 and 36; minor assessments will occur in-between at weeks 6,18, and 30. During the one year Stage IV follow-up, full and minor assessments will occur every three months, again alternating. Minor assessments will occur at 3 and 9 months after the end of Stage III and full assessments at 6 and 12 months after the end of Stage III.

All of your teenager's treatment visits and some of the assessment visits with the study psychologist or study doctor will be audiotaped or videotaped. The tapes will be listened to by other research staff involved in the study to make sure your teenager is getting good care and to help understand how treatment works. These tapes will be stored for five years after the study is completed after which they will be destroyed. Like all research information, these tapes will be stored in a secure location and will be kept confidential.

BENEFITS

A possible benefit of your teenager's participation in this study is that the treatment may help alleviate his or her symptoms of depression. Your teenager will also receive a thorough evaluation of his or her problem. Such a comprehensive evaluation is generally not available with routine care. Additionally, all treatments are provided at no charge.

An indirect benefit may also come from knowing that the results of this study may help improve the future care of teenagers with similar problems. It is possible, however, that your teenager will not gain any direct benefit from being in this study.

It is important that you understand that this study is being conducted for research purposes and does not ensure better or safer treatment nor guarantee individual benefits to the participant. The contribution made by participating in a clinical trial is to further our knowledge about treating adolescents with depression.

ALTERNATIVE TREATMENTS

If you or your teen do not wish to participate, your doctor will discuss other treatment options. The treatments that your teen will receive by participating in this study are available in your community and your teen may be able to receive them without participating in this study. It is possible that you may not receive any better care in this study than you could receive in your community.

RISKS

Teenagers sometimes become upset or frustrated during psychiatric interviewing or filling out questionnaires. However, each of the measures chosen for this study has been used extensively with hundreds of teenagers without ill effects.

Teenagers may also experience mild distress during CBT, as this is a necessary part of learning how to cope more effectively with feelings. However, this risk is minimal as CBT procedures are designed in general to lessen distress. If

necessary, the study doctor will provide up to four (4) additional individual problem-solving sessions to help any teenager that may experience excessive distress during the course of this study.

Most teenagers have few if any side effects from fluoxetine, but nausea, diarrhea, headache, rash, drowsiness, trouble sleeping, and agitation can occur. If a teenager shows unusually high levels of distress or side effects from medication, or requires more than four (4) additional sessions to manage side effects, the doctor may withdraw him or her from the study.

Some teenagers in this study will receive an inactive medication ("sugar pill") during the first stage of the study. Sometimes a person will get better by taking a placebo pill, but there is a higher chance that your teenager will not receive any benefit. There is also a chance that your teenager's symptoms will worsen. For example, your teenager may experience symptoms of low mood, sleep or appetite disturbance, low energy or interest, or suicidal feelings. Throughout the study, the treatment team will frequently monitor your teenager's progress to see if his or her symptoms are worsening. It is important to notify the research team if your teenager looks like he or she is getting worse.

An uncommon but specific side effect of medication treatment for depression is switching from depression to mania. In contrast to depression, which is characterized by sad or low mood and no energy, mania is characterized by high rather than depressed mood and can be accompanied by more energy, becoming very "hyper", super happy, silly or cranky, becoming more talkative, feeling pressured to keep talking, feeling that thoughts are racing, having big ideas, having less need for sleep, feeling overconfident and becoming involved in risky and troublesome activities, such as increased sexual activity or drug use. Your doctor will monitor your teen's mood carefully throughout the study. If mania occurs, he or she will be withdrawn from the study and will be referred for additional interventions outside the study.

Since the medication used in this study may not be healthy for an unborn child, your teen must not be pregnant while in this study. A blood [or urine, depending on site] pregnancy test will be done at the beginning of the study to exclude pregnancy. If pregnant, your teenager and whomever she chooses will be told the results of this test [this clause added depending on state law]and your teen will not be allowed to be in the study. If sexually active, your teen must use proven contraceptive measures for the duration of the study. If she becomes pregnant during the study, your teen will be withdrawn from the medication portion of the study, but may continue with CBT at your teenager's option.

Teenagers who do not improve during Stage I of the study or who relapse at any time will be referred to other mental health providers experienced in the treatment of depression for teenagers. If other treatments (i.e., family therapy, or other medications) are necessary, you or your health insurance company will be responsible for paying for these services.

COMPENSATION

There will be no cost to you or your teenager for being in this study. Medication and visits with the study doctors will be free. You will receive $10 dollars per regularly scheduled visit to cover travel and parking costs. Additionally, you will receive $100 for each assessment visit that is completed. Costs for medical care that is not part of this study will be charged to your health insurance.

CONFIDENTIALITY OF RECORDS

The information gathered as part of this study will be kept in a locked room and/or in a locked file cabinet. In addition to the health care professionals caring for your teenager, the Institutional Review Board (ethics committee) at [site], representatives of Duke University Medical Center and those assigned by them, and the federal agency sponsoring this study may need to review your teenager's medical records At the end of the study, the information will be analyzed using only codes and not names. Scientific publications will not mention your teenager by name.

The researchers have obtained a Certificate of Confidentiality from the Federal Government that will help them protect your privacy, unless you consent in writing to the release of research information. This certificate helps protect your and your teenager's privacy and helps the researchers protect information in your records from being legally accessed for civil or criminal actions, even if the records are sought by the courts or other authorities without your permission. However, if they learn that you or someone else is in serious danger of harm [such as in cases of abuse] they may make disclosures to protect you and/or the other persons.

The research team is required to report certain circumstances such as ongoing child abuse, suicidal or homicidal ideas or intent to authorities. Your teenager's records may be made available to them, even without your consent.

RESEARCH-RELATED INJURY

In the unlikely event your teenager is injured as a direct result of taking part in this study, emergency psychiatric treatment will be made available primarily through [site]. In addition, you will be given help in arranging follow-up care for your

teenager. However, the cost for this treatment will be charged to you or to your health insurance. This study does not provide compensation or payment for this follow-up treatment.

OBTAINING ADDITIONAL INFORMATION

You and your teenager are encouraged to ask questions at any time during this study. If you have further questions about the study, you can call Dr. [Principal Investigator] at [phone number]. Or you may contact an impartial third party, [name], Chairman of the Institutional Review Board, at [phone number]. You may also contact the Institutional Review Board regarding questions concerning your teenager's rights as a research subject.

STATEMENT OF ASSENT

"I have read the above information or it has been read to me. I have had the opportunity to discuss it and to ask questions. I have been informed that I may contact _____or my doctor to answer any questions I may have during this study. I understand the risks and benefits of participating in the study. I know that leaving the study at any time is allowed and will not interfere with my regular care. I will get a copy of this consent form when it is signed. I voluntarily agree to be in this study."

_____ _____

Subject's Signature Date

STATEMENT OF PERMISSION

"I have read the above information or it has been read to me. I have had the opportunity to discuss it and to ask questions. I have been informed that I may contact _____or my doctor to answer any questions I may have during this study. I understand the risks and benefits of my teenager's participation in the study. I know that leaving the study at any time is allowed and will not interfere with my teenager's regular care. I will get a copy of this consent form when it is signed. I agree to allow my teenager to be in this study"

_____ _____

Signature of Parent or Legal Guardian Date

_____ _____

Signature of Person Explaining and Getting Consent Date