Sample Assent/Consent Form for TADS

"Treatment for Adolescents with Depression Study"

PURPOSE

You are being asked to be in a study to help us find out if our treatment is the best way to treat teens like yourself who may be suffering from depression. This study will last about 20 months. Participation is purely voluntary and you do not have to be in the study. You can also change your mind later on without upsetting anyone. Approximately 432 teenagers of either sex, ages 12-17, will be recruited at ten sites in the United States for this study.

PROCEDURES

First, your doctor will determine if you meet the rules to be in the study. This could take up to two half days. Your doctor will talk with you and your parents about yourself and your family, and will ask you to complete some questionnaires. Your doctor will also give you learning tests and a brief physical exam. If you are a girl, you will be asked to give a sample of blood (about one teaspoon) or urine to determine if you are pregnant. You [and your parents, depending on state requirement] and whoever you choose will be told the results of the pregnancy test. If you are pregnant you cannot participate in this study.

If the doctor thinks you meet all the rules for the study and you agree to participate**, y**ou will be assigned to receive one of four treatments. You or the doctor will not be able to decide which treatment you receive. The choice will be based on chance (sort of like flipping a coin) and will be done by a computer. This assigned treatment is planned to last about nine months. The four possible treatments are:

1. Active pill (Prozac) alone
2. Placebo pill ("sugar pill") alone
3. Talking therapy (Cognitive behavior therapy CBT) alone
4. Combination of active pill (Prozac) and CBT

The active pill used in this study is called Prozac. Prozac has been used in the treatment of depression for adults. We are studying how well teenagers do on this medication. You might <u>not</u> receive active medication. You might receive a pill called a placebo that looks like the real medicine, but is not. Neither you nor your doctor will know which type of pill you are taking. There is a one-in-four chance that you will receive placebo.

If you are taking either the active or placebo pill in this study, you will see a medical doctor regularly to see if you need a different dose or if there are any side effects. At first you will see the doctor about every other week, then it will be less if you are doing well. Most visits with the doctor will take about 20 minutes. At the end of 12 weeks (three months), your doctor will be able to find out which treatment you have been given, whether placebo or Prozac, and you will be told. If you have been taking Prozac you will continue to receive Prozac for the remaining six months of the study. If you have been taking placebo and have not gotten better, you will be offered one of the other study treatments of your choice (Prozac, CBT or both).

The talking therapy in this study is called Cognitive Behavior Therapy (CBT). CBT is a therapy that helps you learn new ways to deal with depression. If you are assigned to CBT alone, you will not receive a pill. At first you will have weekly visits with a child psychologist; then the visits will be less frequent if you are doing well. Most CBT visits will take about an hour to 90 minutes. Your parents will attend some visits with you and they will attend some visits alone with the psychologist. CBT continues for nine months.

If you are assigned to the Combination treatment, you will receive both Prozac and CBT. Then you will visit both doctors, one for CBT and one for pills. Combination treatment continue**s** for nine months.

Regardless of which treatment you are receiving, every six weeks you will be asked to fill out more questionnaires like the ones at the beginning of the study and talk with another doctor to see how much you have improved.

Your visits with the study psychologist or study doctor will be audiotaped. These tapes will be listened to by other research staff involved in the study to make sure you are getting good care.

POSSIBLE BENEFITS

It is possible that you will not gain any more benefits from being in this study than you would from getting treatment on your own in your community. However, this study provides a complete evaluation for depression. This information is generally not available with routine care.

All treatments are provided at no charge.

An indirect benefit comes from knowing that the results of this study may help improve the care of other teens with similar problems. It is important that you understand this study is being done so we can learn more about adolescents who are depressed. This study does not promise better or safer treatment than what you could get on your own in the community.

ALTERNATIVE TREATMENTS

Other forms of treatment for depression are available, including other medications and other types of counseling. If you do not wish to participate in this study, your doctor will discuss other treatment options. The treatments that you will receive if you decide to participate in this study may be available in your community and you may be able to receive them even if you do not participate in this study.

RISKS

Sometimes, even with treatment, depression gets worse. It is important that you tell your doctor if you think you are getting worse.

You may become upset or frustrated during interviewing or filling out questionnaires.

You may become upset during CBT, as this is a necessary part of learning how to cope with feelings. However, CBT procedures are designed to minimize difficult feelings. If necessary, extra sessions can be provided by your doctor.

Most persons have few if any side effects from Prozac, but nausea, diarrhea, headache, rash, drowsiness, trouble sleeping, and agitation can occur.

Your doctor may withdraw you from the study if he or she thinks that is in your best interest. If you are withdrawn from the study or do not get better with treatment, your doctors will talk with you about different treatment.

An uncommon but specific side effect of treatment for depression is switching from depression to mania. In contrast to depression, mania is characterized by elevated rather than depressed mood and can be accompanied by more energy, less need for sleep and troublesome activities, such as increased sexual activity or drug use. Your doctor will monitor your mood carefully throughout the study. If mania occurs, you will be withdrawn from the study and will be offered additional interventions outside the study.

For Girls: Since the medication used in this study may not be healthy for an unborn child, you must not be pregnant while in this study. A blood or urine pregnancy test will be done at the beginning of the study to exclude pregnancy. If pregnant, you and whomever you choose [unless otherwise overridden by state law or unacceptable to local IRB] will be told of the results of the pregnancy test and you will not be allowed to be in the study. If sexually active, you must use proven contraceptive measures for the duration of the study. If you become pregnant during the study, you [and your parents] will be told that you must be withdrawn from the medication portion of the study, but may continue with CBT at your option.

You will be told of any changes in the way the study will be done if there are any, and any new risks to which you may be exposed. We will also tell you any new information we learn about depression that may affect your decision to stay in the study.

COMPENSATION

Both the medication and the CBT sessions will be free. There will not be any other charges for the care you receive as part of this study.

You or your parents will receive $10 per regularly scheduled visit to cover travel costs and parking.

Your family also will receive $100 for completing each major assessment visit.

CONFIDENTIALITY OF RECORDS

The information gathered as part of this study will be kept in locked files. In addition to the health care professionals caring for you, your hospital's Institutional Review Board (ethics committee), representatives of Duke University Medical Center, and those assigned by them, and the federal agency sponsoring this trial may need to review your medical records. All information is confidential. However, if we learn that you or someone else is in serious danger of harm (such as in

cases of abuse) we may tell others to protect you and/or the other persons. Scientific publications will not mention any patient by name.

PATIENT RIGHTS

Being in this study is entirely voluntary. You are not required to be in this study, even if your parent wishes it. If you decide not to be in this study, the decision not to participate will not influence your medical care at XXXXXX (facility). You can refuse to participate or can withdraw from the study at any time.

OBTAINING ADDITIONAL INFORMATION

You are encouraged to ask questions at any time in the study. You can ask Dr. _____ at ____-_____ or another staff member the next time you are here. Or you may contact an impartial third party, _____, Chairman of the Institutional Review Board, at ____- _____.

STATEMENT OF ASSENT

"I have read the above information or have had it read to me. I have had the opportunity to discuss it and to ask questions. I know that I may contact my doctor to answer any questions. I understand the risks and benefits to participation in the study. I know that I may leave the study at any time. I will get a copy of this consent form when it is signed. I consent to be in this study."

_____ _____

Subject's Signature Date

_____ _____

Signature of Person Explaining and Getting Consent Date