CONSENT FORM – Cover Sheet

Vilazodone for Separation Anxiety Disorder in Adults Overview of Study

Purpose: To compare the effectiveness of the antidepressant medicine vilazodone, versus placebo, in the treatment of Separation Anxiety Disorder in adults. There have been no published studies of the treatment of Separation Anxiety Disorder in adults.

Procedures:

- Eight visits to the Anxiety Disorders Clinic over a 12-week period Research treatment for 12 weeks:
  - Half of participants will be assigned to take vilazodone (Viibryd), a treatment that is FDA-approved for depression, but has not been previously studied for separation anxiety disorder.
  - Half of participants will be assigned to take a placebo (inactive pill).
  - Assignment to vilazodone or placebo will be done at random (flip of a coin), and you will not find out which you are getting until you end study participation.
  - You will be asked to not start psychotherapy during the time of your participation in this study.

Risks:

- Study medication may not help.
- Side effects may occur.
- Pregnant women should not participate in this study.

Compensation: Up to $300 total for completing all study visits.

Confidentiality: All records will be confidential to the extent permitted by law.

Your Rights: Your participation is voluntary, and you may withdraw from the study at any time and seek alternative treatment if you wish.

CONSENT FORM

Vilazodone for Separation Anxiety Disorder in Adults

Contact for questions and emergencies

Dr. Franklin Schneier or your study doctor is available to answer your questions at any time. They can be reached during the day at (646) 774-7000. After 5 PM you can page the
Anxiety Clinic Doctor on Call at (917) 996-6939. Dr. Schneier can be reached by mail at Unit 69, 1051 Riverside Drive, New York, NY 10032.

PURPOSE OF STUDY

You are being asked to participate in this research study because you are an adult with Separation Anxiety Disorder. This study compares the effectiveness of vilazodone (brand name Viibryd) to placebo in the treatment of 40 persons with Separation Anxiety Disorder. The placebo looks like the other pill, but does not contain any medicine (it is sometimes called a “sugar pill”). There are no published studies of treatments for adults with Separation Anxiety Disorder and no medications approved for this condition. Vilazodone is a medication that is FDA-approved for the treatment of depression but has not been studied for Separation Anxiety Disorder. This study is sponsored by Forest Laboratories, the manufacturer of vilazodone.

ALTERNATIVE TREATMENTS

You do not have to participate in this study to receive treatment for Separation Anxiety Disorder. Vilazodone is available by prescription and can be prescribed by your regular medical doctor. Other treatments for Separation Anxiety Disorder include psychotherapy such as cognitive behavioral therapy, and off-label use of antidepressants, such as

paroxetine (brand name Paxil) or sertraline (brand name Zoloft). Your doctor will discuss benefits, risks and side effects of study participation with you. The alternative to participating in this study would be to get treatment elsewhere without the research interviews and procedures, and without the possibility of getting a placebo.

STUDY PROCEDURES

This study involves your taking study pills daily, and visiting the Anxiety Disorders Clinic up to 8 times (total of 4-1/2 hours) over 12 weeks. You will be assigned at random (flip of a coin, with a 50/50 chance for each) to take either vilazodone or placebo. Neither you nor the researchers will know if you are getting the placebo (inactive pill), but they can find out in an emergency.

You have already met with your study doctor to discuss your medical and psychiatric condition. In addition, you were asked standard questions and received a medical exam, including blood and urine tests, a urine drug screen and an electrocardiogram (EKG).

You will need to be off all psychiatric medication for at least two weeks before starting study treatment, except for the sleep medication zolpidem (brand name Ambien or Ambin CR). If you have been taking zolpidem consistently over the four weeks prior to study treatment, you will be allowed to continue using it during the study. During the study you should not take any medication nor receive any psychotherapy without approval of your study doctor.

If you are taking a medication that has been helpful but is not allowed in the study, you cannot participate in the study. If you are on medication that has not been helpful and is not allowed in the study, your study doctor will ask your permission to contact your treating doctor. If you agree, the medication will be stopped in consultation with your treating doctor. You will be monitored with weekly visits during this period. If you are on medication that has not been helpful and you do not want your treating doctor to be contacted, you will not be able to participate in this study.

To participate in this study, you must agree to avoid using alcoholic beverages or recreational drugs during the study, because they might cause problems if combined with your medication. You must also agree to avoid starting psychotherapy during the study, because it could interfere with evaluating the study medications.

Study Treatment

You will see your study doctor for about 30 minutes weekly for two weeks, and then every other week for six weeks, and then four weeks later. At each visit your study doctor will ask about any improvements or side effects that you have noticed. The doctor will adjust the dose of the medicine to try to maximize your improvement. The doctor will give you study medication (vilazodone or placebo), which you should take as instructed. The medication should not be taken by anyone else, and it should be kept in a safe place out of the reach of children.

You will also be asked about your symptoms by a study rater at each visit. You will also be asked to complete questionnaires at each visit. At three of the study visits, you will also be asked to sit at a computer monitor for about 10 minutes and view pictures of faces and then a pointer ("<" or ">"). You will be asked to press a left or right button, depending on the direction of the pointer.

After 12 weeks of treatment, you will complete the same medical exam you received at the beginning of treatment (physical exam, blood tests [equivalent of two tablespoons], urine tests, EKG). If you are discontinuing study medication you will be given instructions on how to reduce it gradually.

The doctor in charge of the study can remove you from the study without your consent for one of the following reasons:

- If in his judgment, you need an alternative treatment.
- If you fail to follow the study rules.
- If your condition significantly worsens during the study.

Treatment After You End Study Treatment

At the time you end study treatment you will be offered further treatment in the clinic with vilazodone or with another medication if recommended by your clinic doctor, for three months. All visits with your doctor will be free of charge for three months. Medication will be free of charge for the first month, and after that you may have to pay for your medication. After three months you will be referred for follow-up care if needed. If at any time after you end study treatment you would like treatment other than medication you can be referred to such treatment. You can get such treatment while you are receiving the three months of after-study medication treatment offered in the clinic.

When you leave the study, an Anxiety Disorders Clinic doctor will meet with you, inform you whether you were taking vilazodone or placebo during the study, and answer any questions you may have about this.

RISKS

Study Treatments: The main risk of this study is that the research treatments may not help your symptoms. Even if you receive vilazodone, it may not help your Separation Anxiety Disorder, and your symptoms may get worse. A common treatment for Separation Anxiety Disorder includes psychotherapy such as cognitive-behavioral therapy, but it may be up to 17 weeks from the time you enter the study until you would be provided with psychotherapy or another type of treatment, such as other medications. Additionally, because you will not find out whether you have been taking vilazodone or placebo until you leave the study (except in the event of an emergency), decisions about your treatment during the study will not be able to take that information into account.

Other possible risks to you are the side effects that some people get from vilazodone. You should not drive or operate complex or heavy machinery if study medication is affecting your thinking or reflexes. Side effects that may occur include sweating, rash, nausea, vomiting, increased or decreased appetite, weight loss or gain, sleepiness, fatigue, insomnia, dizziness, nervousness, cough, running nose, dry mouth, muscular tremors, changes in heart rate, elevated mood, and sexual problems, including

loss of interest for both sexes, difficulty having orgasm in women, and difficulty having an erection or ejaculating in men. Vilazodone may cause unexpected problems if combined with other medications you might take during the study.

Stopping vilazodone too rapidly may cause dizziness, agitation or anxiety, nausea and sweating. These symptoms usually resolve over time. You should not stop study medication before discussing it with your study doctor.

While vilazodone is considered to be a safe treatment, the Food and Drug Administration (FDA) has issued a public health advisory about a possible link, in rare cases, between suicidal thoughts or behavior in patients treated with antidepressant medications (including vilazodone). The FDA has asked health care providers and patients to note that worsening of depression could be related to the underlying disease process, or in some cases, might be a direct result of antidepressant drug treatment. At the present time, the FDA has not concluded that these drugs cause worsening depressive symptoms or suicidal ideation or behavior, and this is an area of active research. The FDA advisory urges careful monitoring of patients receiving these medications during the beginning stage of therapy and during increases or decreases in dosage.

To minimize risks of study treatment, you have been checked for conditions that can increase risks of treatment, and you will be closely monitored for side effects at every visit. A study doctor will be available by pager 24 hours/day. Your study doctor can adjust the doses of study medications to minimize side effects. If you need to take any other medications during the study, you should first contact your study doctor to minimize the risk of drug interactions. You may leave the study at any time. In the event of a medical emergency, your doctor will be able to find out what medication you have been taking during the study.

For women: **You should not be in this study if you are pregnant.** Women who take vilazodone during pregnancy or who become pregnant while taking it may be at greater risk of having a baby born with a birth defect. You must agree to use birth control

throughout the course of your treatment with medication. If you decide to stop using birth control, or if there is a possibility that you are pregnant during the study, you must tell your study doctor immediately so that a pregnancy test can be done, and we can decide whether you should continue in the study.

Blood Drawing may cause mild discomfort and, rarely, a small arm bruise, clot or infection may occur at the site.
Ratings: You may feel mild to moderate upset or frustration due to answering questions about your life or filling out questionnaires. Study staff are skilled at dealing with these events and will try to help you feel as comfortable as possible (e.g., by giving breaks during an evaluation, offering encouragement).

BENEFITS:

A direct benefit to you is the possibility that the research treatment **may** help your Separation Anxiety Disorder symptoms. In addition, your participation may help researchers learn more about how to treat Separation Anxiety Disorder. There may be no benefit to you if the treatment is not effective.

COMPENSATION:

You will receive $60 for each of the first and last visits, and $30 for each of the **6** interim visits you complete, to be paid in cash after the completion of each visit (up to $300 total), as payment for your time. You will be paid for each of these visits that you complete on schedule, whether or not you are continuing on study treatment.

CONFIDENTIALITY:

All records related to the study are confidential, although state and federal agency, and Forest Laboratories personnel may inspect records. Similarly, there are legal advocacy organizations that have the authority under the law to access otherwise confidential

subject records. They cannot re-disclose this information without the subject's consent. All records will be confidential to the extent permitted by law. Your records will be kept in locked files and access will be allowed only to members of the research team, or institutional personnel as part of a routine audit. Should any of the information gathered from you be used for scientific publications or presentations, you will be protected through the use of a system of codes that will not reveal the identity of individuals. Any report based on this study will only be used as grouped information without mention or description of the individual participants.

Your name and other personal identifying information will be stored in an electronically secure database at New York State Psychiatric Institute. Research data that is entered into the computer will be stored according to study ID number. A master list linking the patient name to the assigned ID number is kept in a separate file. To access the computer and appropriate data files, the staff member must have knowledge of the password and be given rights to access the data by the data manager. All data that is transmitted via computer is encoded and identifying information is removed.

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

RESEARCH STANDARDS AND PARTICIPANTS' RIGHTS:

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate will not effect your treatment at the New York Psychiatric Institute. The doctors participating in this research study are also responsible for your clinical care in the Anxiety Disorders Clinic, even after you end the study. You will be notified of significant new findings that may relate to your willingness to continue to participate in the study.

Medical Compensation for Research-Related Injuries

Federal regulations require that you be informed about the institution's policy with regard to compensation and payment for treatment of research-related injuries. Short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute will be provided. In addition, you will be provided assistance in arranging follow up care in such instances.

New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that participation in this research does not waive any of your legal rights to seek such compensation through the courts.

Dr. Schneier or your study doctor is available to answer your questions about the study at any time. They can be reached during the day at (646) 774-7000. After 5 PM you can page the Anxiety Clinic Doctor on Call at (917) 996-6939. In addition, an emergency psychiatric consultation is always available to you by calling these numbers. The doctors participating in this research study are also responsible for your clinical care. If you have any questions about your rights as a research participant or any complaints, you may call the NYSPI-IRB Main Office at (646) 774-7155 during regular office hours.

You will be given a copy of the signed Consent Form to keep.

STATEMENT OF CONSENT

I voluntarily agree to participate in the research study described above.

NAME_____(print)

Date_____ Signature _____

Study Participant

I have discussed the proposed research with the patient, and in my opinion, this patient understands the benefits, risks and alternatives (including non-participation) and is capable of freely consenting to participate in this research.

NAME_____(print)

Date _____Signature_____

Study Physician