Study Title:	**Eszopiclone for the Treatment of PTSD**
Sponsor:	**National Institute of Health (NIH)**
Study Investigator:	**Mark H. Pollack, M.D.** **1645 W. Jackson Blvd.** **Suite 600** **Chicago, IL 60612** **312-942-5000**

RUSH

Subject Information Sheet and Consent Document

Introduction

Note: If you are the parent, guardian, or legal representative of a (minor or person who is not able to consent for themselves) the terms "you" or "your" refer to you and/or the research subject.

This form provides you with information so you can understand the possible risks and benefits of participating in this study; so that you can decide whether or not you want to be a part of this research study. Before deciding whether to participate in this study, you should read the information provided on this document and ask questions regarding this study. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate.

Why are you invited to participate in this study?

You are being asked to take part in this study because you may have post-traumatic stress disorder-related sleep disturbance.

Research studies include only people who choose to take part. Please take your time to make your decision and discuss it with your friends, family and/or physician. Remember that your participation is completely voluntary. There is no penalty if you decide not to take part in this study or decide later that you want to stop participating in this research study. Your care at Rush University Medical Center will not be affected if you decide not to participate.

What is the purpose of this study?

The purpose of this study is to find out if eszopiclone is effective and tolerable for people with post traumatic stress disorder (PTSD)-related sleep disturbance.

Eszopiclone (Lunesta®) has been approved by the US Food and Drug Administration (FDA) for the treatment of insomnia (inability to sleep). Eszopiclone has not been specifically approved by the FDA for people who have PTSD-related sleep disturbance.

This study uses a placebo. A placebo looks exactly like eszopiclone but contains no active drug.

The following things will happen during your Baseline Visit:

- Your vital signs (blood pressure, temperature, height, weight, and heart rate) will be measured.
- We will assess the severity of your symptoms and use this information to place you in one of two study drug groups.
- About 1 tablespoon of blood (20 mL) will be drawn for immunology tests. Specifically, we will assess the part of blood involved with inflammation (the body's response to irritation or injury).
- We will ask you questions about your current psychological symptoms and sleep cycles.
- We will administer a memory test.
- You will fill out 4 questionnaires about your sleep, social history, and personality. It will take you about 15 minutes to complete these questionnaires. We hope you will answer all questions, but you can skip over any you do not want to answer.
- Your daily sleep diaries will be reviewed, and you will be given additional diaries to complete until your next study visit.
- The doctor will review your current drugs and supplements for any side effects you may be experiencing.
- The study drug will be given to you with instructions. You will be instructed to take the study drug immediately before going to bed, and only if you can dedicate 8 hours to sleep. You should not take the study drug with alcohol or with other sedating drugs.

Study Weeks 1 – 10 (Visits at Weeks 1, 2, 3, 4, 6, 8, and 10) – Treatment Phase

- Your vital signs (blood pressure, temperature, height, weight, and heart rate) will be measured.
- We will ask you questions about your current psychological symptoms and sleep cycles.
- The doctor will review your current drugs and supplements for any drug side effects you may be experiencing.
- Your daily sleep diaries will be reviewed, and you will be given additional diaries to complete until your next study visit.
- At the Week 10 visit, you will be required to wear a wrist activity monitor to record your sleep. You will be instructed to wear the monitor the week before the treatment phase ends (week 11-12).
- The study drug will be given to you with instructions to take the study drug immediately before going to bed, and only if you can dedicate 8 hours to sleep. You should not take the study drug with alcohol or with other sedating drugs.

Study Week 12

- Your vital signs (blood pressure, temperature, height, weight, and heart rate) will be measured.
- We will ask you questions about your current psychological symptoms and sleep cycles.
- The doctor will review your current drugs and supplements for any drug side effects you may be experiencing.
- Your daily sleep diaries will be reviewed, and you will be given additional diaries to complete until your next study visit.

treatment for post-traumatic stress disorder and/or sleep disturbance. Do not take any new drugs or dietary supplements without first talking to the study doctor.

What are the possible risks of the study?

Study Drug Risks

The most common side effects associated with eszopiclone are headache and an unpleasant taste in your mouth.

Less common side effects include:

- drowsiness
- dizziness
- anxiety
- nervousness
- confusion
- depression
- hallucinations (imagining something that is not really there)
- abnormal dreams

Other less common side effects include dry mouth, swelling of your hands or feet, chest pain, migraine headache, decrease in sexual interest, upset stomach, nausea or vomiting, rash, or itching. Sometimes individuals may experience a period of a few days or a week or two of worsening of sleep symptoms after stopping the drug.

You should use caution while driving a car or operating machinery while taking part in this study because the study drug may make you drowsy. You may **not** drink alcoholic beverages while you are taking the study drug. It is possible that the combination of alcohol and the study drug may cause unknown side effects.

Emotional Risks

Some subjects may feel uncomfortable discussing their traumatic experiences and symptoms. You do not have to answer any questions that make you uncomfortable.

Blood Drawing Risks

You may feel some pain associated with having blood drawn through a vein. You may experience discomfort, bruising, and/or other bleeding at the site where the needle is inserted. Sometimes people get dizzy or feel faint when their blood is drawn. Very rarely, the vein in which the needle has been inserted may become inflamed or infected, which can be treated.

Are there any anticipated pregnancy risks?

Women

If you are pregnant or breastfeeding, you cannot take part in this study. A pregnancy test is required and will be given at screening. You are responsible for using an effective birth control method such as birth control pills, barrier method (such as condoms or diaphragms), intrauterine device (IUD), hormone implants or surgical sterility while you are taking part in this study. Once you have completed treatment, you may discontinue birth control after completion of treatment. If you become pregnant, you must notify the study doctor immediately.

What are the costs of your participation in this study?

There will be no cost to you for taking part in this study. All clinic fees, professional fees, diagnostic and laboratory fees that are part of this study, including physical examinations, blood tests, pregnancy test, drug test, and ECG will be provided at no cost to you. The study drug (eszopiclone or placebo) will be given to you free of charge.

The cost of your ongoing routine medical care, which is not part of this research study, will be billed to you or your health insurance company in the normal way.

Will you be paid?

In return for your time and effort, you will be paid up to $60 in cash for taking part in this study. You will be paid $30 at baseline if the following procedures are completed: lab test at screening visit ($10), memory test at screening visit ($10), and lab test at baseline ($10). In addition, you will be paid $30 at the end of the follow-up visit. Your parking or public transportation will be reimbursed at each visit, including the screening visit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company.

If you have any medical problems during the study, please contact the study doctor, they will explain your treatment options to you or tell you where you can get treatment.

Neither Rush University Medical Center nor the National Institutes of Health (NIH) has a program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you inform emergency personnel of your participation in this study.

Procedures to ensure your safety

People with PTSD may sometimes feel worse and become withdrawn and not want to talk. If this happens, it is very helpful and, at times, lifesaving, for the study doctor to be able to speak to a family member, friend or therapist. These people can inform the study doctor about you condition. To help make sure that you are safe while taking part in this study, we are asking you to choose someone that we can contact. Choosing someone the study doctor can contact is optional. You do not need to choose someone in order to participate in the study.

We will send him/her a brief summary of informational about post-traumatic stress disorder and your participation in this study. We may also contact this person if we are concerned about your health and unable to reach you. Please write below the name, address and telephone number of a relative, friend or therapist who knows you well and can contact the study staff in case of emergencies.

Signature of the Principal Investigator

Date of Signature