

## INFORMATION AND CONSENT FORM

**Protocol Title:** Clinical Study To Evaluate The Ability Of MUSE To Decrease Erectile Function Recovery Time in Post-Radical Prostatectomy Patients

**Protocol #:** RP-01

**Sponsor:** VIVUS, Inc.

**Study Doctor:** Jason D. Engel MD  
Urologic Surgeons of Washington  
2021 K St. NW, Ste. 408, Washington, DC 20006

**Telephone Number:** (202) 361-4886 or (202) 223-1024

**After Office Hours:** (202) 361-4886 or (202) 223-1024

The study doctor wants to know if you would like to be part of a research study. This form describes the study in order to help you decide if you want to participate. This form will tell you what you will have to do during the study and the risks and benefits of the study.

If you have any questions about or do not understand something in this form, you should ask the study doctor. You should discuss your participation with anyone you choose in order to better understand this study and your options. Do not sign this form unless the study doctor or study staff has answered your questions and you decide that you want to be part of this study.

Being in this study does not replace your regular medical care.

When reading this form, please note that the words “you” and “your” refer to the person in the study rather than to a legally authorized representative who might sign this form on behalf of the person in the study.

### WHAT IS THIS STUDY ABOUT?

You are scheduled to have radical prostatectomy surgery for prostate cancer. A common complication from this surgery is erectile dysfunction that can be temporary or permanent. In cases where erectile dysfunction is temporary, it may take 12 months or longer for normal erectile function to return.

Oral medications such as Viagra® may not work as well in men who have had a radical prostatectomy because of possible nerve damage caused by the surgery. Such nerve damage can prevent or reduce the effects of a drug like Viagra.

Researchers want to find out if a drug given directly into the urethra, known as MUSE (Medicated Urethral System for Erection), can help men with erectile dysfunction associated with radical prostatectomy. The active ingredient in MUSE is alprostadil, or prostaglandin E1, a component found naturally in the body and especially in semen. The alprostadil in MUSE is inserted into the urethra 5 to 10 minutes before initiating sexual intercourse.

Participant's Initials \_\_\_\_\_ Date \_\_\_\_\_  
Partner's Initials \_\_\_\_\_ Date \_\_\_\_\_  
Version 1, dated 05/19/05  
Page 1 of 9

The study doctor will give MUSE to some men in this study to see if it can help them reduce the time it takes them to get an erection. Another purpose of this study is to find out if using MUSE after radical prostatectomy surgery can reduce the time needed to get an erection when using Viagra later as needed. The U.S. Food and Drug Administration (FDA) has approved Viagra and MUSE for use in men to treat erectile dysfunction.

It is planned that about 125 men who will have a radical prostatectomy, have erectile dysfunction after surgery, and are at least 18 years old will be in this study.

### **IS THERE ANYTHING ELSE I CAN DO FOR MY ERECTILE DYSFUNCTION ASSOCIATED WITH RADICAL PROSTATECTOMY?**

You do not have to be in this study to get help for your erectile dysfunction. The study doctor will talk to you about other things you can do for erectile dysfunction. Some other things you can do are:

- take oral erectile dysfunction medications such as Viagra or others outside of this study
- use MUSE outside of this study
- get intracavernosal injections
- use vacuum pumps
- have injections of drug directly into the penis
- use constricting bands
- have penile vascular surgery
- have a penile prosthesis implanted

### **WHO IS PAYING FOR THIS STUDY?**

A company called VIVUS, Inc. has provided an unrestricted educational grant to help pay for this study and to pay the study doctor to do this study.

### **WILL IT COST ANYTHING TO BE IN THIS STUDY?**

While you are in the study, you still need to get regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study. **Your regular medical care will include radical prostatectomy surgery.**

You do not have to pay for study drugs, study visits, or tests that are part of the study. To find out more about costs, you can ask the study doctor or study staff.

You may have to pay the costs of diagnosing and treating a condition or injury that you or others think is a direct result of your being in the study. This could happen if:

- the sponsor and/or the study doctor do not think the condition or injury is a direct result of your being in the study
- you have not followed the directions the study doctor or study staff gave you about the study

Participant's Initials \_\_\_\_\_ Date \_\_\_\_\_

Partner's Initials \_\_\_\_\_ Date \_\_\_\_\_

## HOW LONG WILL I BE IN THE STUDY?

If you decide to be in this study and the study doctor says you can be in the study, your participation will last about 11 months. You will have to come to the study center about 8 times during the study. The study staff will tell you when to come in for your study visits. You should ask the study staff how long your visits will last.

## WHAT WILL HAPPEN DURING THIS STUDY?

If the study doctor says you can be in the study and you want to be in the study, the study doctor will give you tablets to swallow or MUSE to insert into your urethra every night for 9 months.

In addition, you will be given Viagra tablets to swallow as necessary, regardless of which study group you are in.

You will be assigned by chance (like flipping a coin) to 1 of the 2 study groups:

- Group 1: Viagra at a dose of up to 100 mg
- Group 2: MUSE at a dose of up to 250 mcg

There is a 2 out of 3 chance you will get MUSE and a 1 out of 3 chance that you will get Viagra.

You are the only one who should use MUSE and/or take Viagra. You should make sure that no one else uses it or takes it.

While you are in the study, you must:

- Follow the instructions you are given.
- Not use any other treatment(s) for your erectile dysfunction
- Come to the study center for all visits with the study doctor.
- Tell the study doctor or study staff about any changes in your health.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

## What happens when I come for study visits?

Before you can start the study, the study doctor or study staff will talk to you about the study. Then you have to sign this form before the study doctor or study staff can begin the procedures for the study.

You will sign a separate consent form for the radical prostatectomy surgery.

After you sign this form, the study doctor or study staff will do the things listed below when you come in for study visits. If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

- **Health and Medication Questions:** Ask you to answer questions about your health and the medications you take.
- **Physical Exam:** Do a physical exam. You should ask the study doctor about what will happen during this exam.
- **Questionnaires:** Ask you to fill out questionnaires about your erectile dysfunction.
- **Penile Length Assessment:** Measure the length of your stretched penis.

Participant's Initials \_\_\_\_\_ Date \_\_\_\_\_

Partner's Initials \_\_\_\_\_ Date \_\_\_\_\_

- **Study Diary:** Give you a study diary and tell you how to use it.
- **Study Drug:** Give you a supply of study drug and tell you how and when to use it or take it. Ask you to bring back all unused study drug to each visit.
- **Viagra:** Give you a supply of Viagra and tell you how and when to take it.

Your regular medical care might include some of the study tests and procedures. The study doctor or a member of the study staff can answer any questions you may have about the tests and procedures that are not part of your regular medical care.

After the study is over, you should talk to the study doctor about your future treatment for erectile dysfunction.

## **ARE THERE RISKS TO ME IF I AM IN THIS STUDY?**

### What can happen if I take Viagra?

Some men who have taken Viagra had the following side effects:

- headache
- flushing
- dyspepsia (upset stomach)
- nasal congestion
- urinary tract infection
- abnormal vision
- diarrhea
- dizziness

If you are taking an alpha blocker (Hytrin or Flomax) because you have difficulty urinating, talk to the study doctor. Low blood pressure has been reported with the combination of alpha blockers and drugs like Viagra.

### What can happen if I use MUSE?

Some men who have used MUSE had the following side effects:

- penile pain
- urethral burning
- testicular pain
- minor urethral bleeding or spotting

Please tell the study doctor or study staff right away if you have any of these side effects. Please tell them if you have any other problems with your health or the way you feel during the study.

### Could I have an allergic reaction?

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction are:

- a rash

Participant's Initials \_\_\_\_\_ Date \_\_\_\_\_

Partner's Initials \_\_\_\_\_ Date \_\_\_\_\_

- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

Could I have any other problems with my health if I do this research study?

It is possible that problems and side effects of Viagra and MUSE that nobody knows about could happen to you, which include your erectile dysfunction getting worse or even death. If the study doctor learns any new information about Viagra and MUSE that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

It is possible that taking Viagra and MUSE with your regular medications or supplements may change how Viagra and MUSE, your regular medications, or your regular supplements work. It is very important that you tell the study doctor about all medications or supplements you are taking during the study.

**WILL BEING IN THIS STUDY HELP ME?**

The study drugs may help your erectile dysfunction, but there is no guarantee that being in this study will help you. Your erectile dysfunction might not get any better or may even get worse while you are in this study. Information from this study might help researchers to come up with new tests or medications to help others in the future.

**DO I HAVE TO BE IN THIS STUDY?**

Your decision to be in this study is voluntary. You don't have to be in the study if you don't want to, and you can change your mind at any time. There will be no penalty to you, and you will not lose any benefits except for benefits having to do with the study. Your regular medical care at this study center will not change if you decide not to be in the study.

If your partner decides not to be in the study, you will not be allowed to continue in the study.

The study doctor or sponsor can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- The study doctor believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The sponsor stops the study for any reason.

If you want to stop being in the study, tell the study doctor or study staff and return all unused study drug and study materials. If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help your removal from the study happen safely, you may be asked to participate in more tests.

Participant's Initials \_\_\_\_\_ Date \_\_\_\_\_

Partner's Initials \_\_\_\_\_ Date \_\_\_\_\_

## WHO WILL USE AND SHARE INFORMATION ABOUT MY BEING IN THIS STUDY?

This section explains who will use and share your study-related health information if you agree to be in this study. If you do not sign this form, you cannot be in the study.

During the study, the study doctor and study staff will use, collect, and record health information about you (your "records"). Your records include any information about you that the study doctor needs to do the study, including information from the tests described above. Your records also will include other identifying information about you, such as your name and address.

If you sign this form:

- You allow the study doctor and study staff to use your records to carry out this study.
- You allow the study doctor to share your records with the sponsor, VIVUS, Inc.; people who work with or for the sponsor; and other researchers involved in this study. These people will use your records to review the study, and to check the safety and results of the study.
- You allow the study doctor or sponsor to use some facts about your being in this study in books, magazines, journals, and scientific meetings. If this happens, no one will use your name.
- You allow the study doctor to share all of your records and this signed consent form with government agencies, including the U.S. Food and Drug Administration (FDA) and other government agencies in the U.S. and other countries. The study doctor may also share your records with regulatory agencies, like Quorum Review Institutional Review Board (IRB). These agencies may use your records to check the study information, how researchers are doing the study, participants' safety, and the results of the study.
- You allow the study doctor to share your records with your health care payer to resolve your claim if you are hurt because of being in this study. If this happens, the study doctor or the sponsor may share your records with their insurance carriers to resolve your insurance claim, and the study doctor may also request medical records from your other health care providers to learn more about your condition.

There are national and state laws that make the study doctor protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the need to share your information. After the study doctor shares your records with the sponsor and others, the laws may no longer protect the privacy of your records. The sponsor or others may share your records with other people who do not have to protect the privacy of your records.

If you would like to know how the sponsor will protect the privacy of your records, ask the study doctor how to get this information.

You have the right to see and copy your records. However, if you sign this form, you might not be able to see or copy some of your records until after all participants finish the study.

You can cancel this consent to use and share your records at any time. If you want to cancel your consent, you must write a letter to the study doctor. If you cancel your consent:

- You will not be able to be in the study.

Participant's Initials \_\_\_\_\_ Date \_\_\_\_\_

Partner's Initials \_\_\_\_\_ Date \_\_\_\_\_

- The study doctor will not be able to use or share your records unless it is necessary to protect the integrity of the study.

This consent to use and share your records does not have an expiration date. If you do not cancel this consent form, then the study doctor and the study staff will be able to use and share your records for as long as they want to.

You will receive a signed copy of this form for your records.

### **WILL I GET PAYMENT?**

You will not get payment for being in this study.

### **WHAT IF I GET HURT OR SICK WHILE I AM IN THE STUDY?**

If the study drugs, taken as directed in the protocol (study plan) for this study, result in physical injury, procedures necessary for the immediate diagnosis and treatment of such injury will be available at no cost to you. No other compensation is routinely available, and all other medical treatment will be your responsibility. Every effort will be made to prevent physical injury that could result from this research. The study doctor can talk to you about medical treatment in case of complications.

To ask questions about this, talk to the study doctor or study staff.

### **WHO CAN I TALK TO ABOUT THE STUDY?**

You can ask questions about the study any time. You can call the study doctor at any time. You should call the study doctor if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

Study Doctor: Jason D. Engel MD  
Telephone Number: (202) 361-4886 or (202) 223-1024  
After Office Hours: (202) 361-4886 or (202) 223-1024

Quorum Review Institutional Review Board (IRB) reviewed this study. An institutional review board (IRB) is a group of people who review research studies to protect the rights and welfare of research participants. If you have questions about what it means to be in a research study or about your rights as a research participant, you can call Quorum Review IRB or visit the Quorum Review IRB website at [www.quorumreview.com](http://www.quorumreview.com).

Quorum Review IRB is located in Seattle, Washington.  
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.  
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

**DO YOU AND YOUR PARTNER WANT TO BE IN THIS STUDY?**

Please check one box:

- Yes, my partner and I want to be in the study.
- No, my partner and I do not want to be in the study.

My partner and I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with us about this study. They have answered all our questions. We voluntarily agree to be in this study. We agree to allow our records related to this study to be used and shared as described above.

By signing this form, we have not given up any of our legal rights as research participants. We will get a signed copy of this consent form for our records.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Participant's Partner

\_\_\_\_\_  
Signature of Participant's Partner

\_\_\_\_\_  
Date

I certify that under state law I am the legally authorized representative of the Participant named above and that I am authorized to sign this consent to his/her participation in the research study described above. I am also authorized to allow the use and sharing of the Participant's records as described above.

\_\_\_\_\_  
Printed Name of Participant's Legal Representative

\_\_\_\_\_  
Signature of Participant's Legal Representative

\_\_\_\_\_  
Date

I certify that under state law I am the legally authorized representative of the Partner of the Participant named above and that I am authorized to sign this consent to his/her participation in the medical research study described above. I am also authorized to allow the use and sharing of the Participant's Partner's records as described above.

Participant's Initials \_\_\_\_\_ Date \_\_\_\_\_

Partner's Initials \_\_\_\_\_ Date \_\_\_\_\_

\_\_\_\_\_  
Printed Name of Participants' Partner's Legally Authorized Representative

\_\_\_\_\_  
Signature of Participant's Partner's Legal Representative

\_\_\_\_\_  
Date

I attest that the Participant, the Participant's partner, and/or the Participant/Participant's Partner's legal representative named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

\_\_\_\_\_  
Printed Name of Person Explaining Consent

\_\_\_\_\_  
Signature of Person Explaining Consent

\_\_\_\_\_  
Date

I attest that I or my representative discussed this study with the Participant, Participant's Partner, and/or legal representative(s) of the participant or the Participant's Partner named above.

\_\_\_\_\_  
Signature of Principal Investigator or Sub-Investigator

Participant's Initials \_\_\_\_\_ Date \_\_\_\_\_

Partner's Initials \_\_\_\_\_ Date \_\_\_\_\_