APPROVED
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WIRB®

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: LAPAROSCOPIC PROSTATECTOMY FOR CHRONIC PROSTATITISA Phase II Non-Randomized Clinical Trial

PROTOCOL NO.: 1
WIRB® Protocol #20081635

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This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the study doctor or study staff explain the research study to you,
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study could affect your current or future insurance coverage.

After reading and discussing the information in this consent form, you should know:

- Why this research study is being done;
- What will happen during the research;
- What drug or device or procedures will be used;
- Any possible benefits to you;
- The possible risks to you;
- The other medical procedures, drugs or devices that could be used instead of being in this research study; and
- How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

BACKGROUND AND PURPOSE OF THE STUDY

The symptoms of chronic (type III, non-infectious) prostatitis are commonly treated with such medications as antibiotics, alpha-blockers, and more. They are also treated with prostate injections and massage. However, the symptoms of chronic prostatitis can be impossible to eliminate with medications and injections.

In the few cases treated, laparoscopic prostatectomy has been effective in eliminating the symptoms of chronic prostatitis that did not respond to the kind of conventional treatments listed above. **However, there is no body of scientific evidence regarding laparoscopic prostatectomy for chronic prostatitis. This means that there is no basis on which to evaluate the likelihood (probability) that laparoscopic prostatectomy will work and/or to know the amount of symptom relief with laparoscopic prostatectomy.**

This study is being done to better evaluate the amount of change in the symptoms associated with chronic prostatitis after laparoscopic prostatectomy. It is also being done to help identify factors that can tell us which patient with chronic prostatitis is most likely to experience improvement of his symptoms after laparoscopic prostatectomy.

As part of this study, you will be observed for 6 months after your prostatectomy. About 50 men will be in this study.

PROCEDURES

- You will be treated with laparoscopic prostatectomy. Dr. Krongrad will discuss the details of that procedure with you and you will be given a surgical consent to sign.
- Before and after the procedure you will complete a questionnaire. This is the research (experimental) part of the study.
- No placebo or sham procedure will be used.

RISKS AND DISCOMFORTS

Laparoscopic prostatectomy is a standardized surgical procedure that is known to be associated with these risks:

- **Infertility:** laparoscopic prostatectomy causes infertility: inability to father children. You should discuss this study plan with any woman you plan to impregnate, because your participation in the study will make you infertile and will possibly have a negative effect on her. **If you would like to consider fathering children in the future, you should <u>bank sperm before having the procedure.</u>**

- **Pain:** all surgical procedures cause some pain. Laparoscopic prostatectomy requires an average of two Tylenols® for pain relief in the first 24 hours.

- **Incontinence:** there is a chance of incontinence: involuntary loss of urine. It is very unlikely that you will have permanent incontinence but you will probably have temporary incontinence.

- **Impotence:** there is a risk of losing erections, the physical response to erotic stimuli. The likelihood of this varies as a function of age, baseline function, smoking history, obesity, medications, illness, depression, and more.

- **Scarring:** there is a small chance of scar formation at the line at which the bladder is reconnected to the urethra, which can interfere with the flow of urine. If this happens, it may require a short procedure to correct.

- **Cardiovascular:** any surgery involving anesthesia, including laparoscopic prostatectomy, is associated with risk of heart attack, stroke, and even death. The risk varies with many factors, including age, obesity, smoking history, and the like.

- **Conversion:** all laparoscopic procedures can end up as open surgical cases. In Dr. Krongrad's experience this risk is approximately 0.1 percent.

- **Infection:** this is a very rare complication and usually means a simple urinary tract infection that can be treated with antibiotics.

- **Injury:** It is possible that adjacent organs, such as the rectum and ureters, will be injured. If this happens it may require additional surgery to repair.

- **Bleeding:** any surgical procedure can be associated with bleeding. With laparoscopic prostatectomy there is minimal bleeding and transfusion is uncommon.

- **Persistence, Worsening, and Recurrence of Symptoms:** It is possible that your prostatitis symptoms will not improve after the procedure. It is also possible that they will worsen. It may be that the symptoms will disappear and then return.

There may be side effects that are not known at this time.

There is no risk in completing questionnaires.

NEW INFORMATION
You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
Your prostatitis may improve while you are in this study; however, this cannot be promised. The results of this study may help people with prostatitis in the future.

COSTS
You will not be billed for administration of the two symptom questionnaires, because these are the research procedures.

You or your insurance company will be billed for the laparoscopic procedure.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include the costs of treating side effects from the surgical procedure. Otherwise, you might have unexpected expenses from being in this study.

PAYMENT FOR PARTICIPATION
You will not be paid for taking part in this study.

ALTERNATIVE TREATMENT
If you decide not to enter this study, there is other care available to you, such as antibiotics, alpha-blockers, and/or prostate massage. The study doctor will discuss these with you. You do not have to be in this study to be treated for prostatitis.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information gathered for this research about:
  Questionnaires
- Records about the laparoscopic prostatectomy you received

Who may use and give out information about you?
The study doctor and the study staff.

Your information <u>may</u> be given to:

- Department of Health and Human Services (DHHS)
- The National Institutes of Health
- The Hospital Corporation of America
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results,
- to publish the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

- Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

COMPENSATION FOR INJURY
If you are injured or get sick as a result of being in this study call the study doctor immediately. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Taking part in this study is voluntary. You may decide not to take part or you may leave the study at any time. Your decision will not cause any penalty or loss of benefits to which you are entitled.

The study doctor or the sponsor may stop your participation in this study at any time without your consent for any of the following reasons:

- it is in your best interest;
- you do not later consent to any future changes that may be made in the study plan;
- or for any other reason.

SOURCE OF FUNDING FOR THE STUDY
The Krongrad Institute is paying for the collection, storage, analysis, and publication of research results.

QUESTIONS
Contact Arnon Krongrad, M.D. at 305-936-0474 (24-hour pager) for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you want to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT
I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name

CONSENT SIGNATURE:

Signature of Subject (18 years and older)	Date
Signature of Person Conducting Informed Consent Discussion	Date