Study Title: Feasibility Testing of Transpelvic Magnetic Stimulation as a Novel Intervention to Improve Urogenital Function in Prostate Cancer Survivors (NCT04488068)

Principal Investigator: M. Raj Rajasekaran, PhD

VA Facility: San Diego VA Healthcare System

Participant Name:	Date:

STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

Dr. Rajasekaran, Dr. Sakamoto and their associates are conducting a research study to reduce and/or prevent the leakage of urine after prostate surgery and possibly to prevent sexual dysfunction caused by surgery. You have been asked to participate because you are enrolled for prostate surgery, which is associated with a high chance of incontinence and sexual dysfunction. There will be approximately 20 participants at this San Diego VA site. All the patients will be instructed by Dr. Sakamoto to perform pelvic muscle exercise. The patients will be randomly assigned either to a sham stimulation protocol (ten) or a true pelvic muscle magnetic stimulation (ten). Your chances of being assigned to either the non-treatment or treatment group are equal, just like flipping a coin. All patients will be evaluated on a regular basis and will undergo same diagnostic procedures such as MRI and blood flow changes. The data from sham therapy subjects will be used to evaluate the difference treatments make on sexual or urinary incontinence function. You will be unaware group to which you are assigned to.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

You will be assigned into one of two groups: treatment or non-treatment. Your chances of being assigned to either the non-treatment or treatment group are equal, just like flipping a coin. If you agree to be in the study, the following will happen to you (independent of the group- no treatment or treatment group):

a. In first, week 4, week 8 and last visit (week 13), you will complete a urinary symptom and sexual function questionnaires.

b. You will undergo MR imaging during the first and last (week 13) visits. From first visit onwards (twice a week), you will be positioned on a chair (all sessions).

c. Blood flow measurement will be positioned in the groin area (only during the first, 4 8, and week 13) using two machines (ultrasound and Laser device).

d. For magnetic stimulation you will be seated in a chair with a magnet placed below the seat. The magnet will be pulsed and the muscles in the groin area will be activated to provide exercise to the muscles in that area (if you are in the no treatment group, you will not be exposed to the magnetic treatment). In the no treatment group, the device will be set up in a similar way as in the treatment group, but no effective energy will be delivered. Your muscles will be stimulated for short periods, but the machine becomes hot and will required to cool off before restarting, therefore requiring you to remain seated for about an hour.
e. The entire procedure will be completed in less than 1.5 hours.
f. After completion of these procedures, you will be free to go home.

Thus, your participation during each session will take approximately 1 to 1.5 hours each time you come to the VA hospital, and you will be expected to come to the hospital 15 times over a 3-month period. Each subject will participate for total of 6 months, but the entire study duration will be two years. All the described research procedures are done for gathering information on the effectiveness of magnetic stimulation to improve sexual function and improve urinary incontinence.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

If you do not have these symptoms or cannot come to the hospital for the treatment sessions, then you should not enroll. There are no alternatives to this study other than to follow the standard pelvic muscle exercises as suggested to you by your urologist.
Participation in this study may involve some added discomforts. The procedures used are likely to cause:
a. Minor discomfort from using the magnetic probe. This may cause some tingling sensation in the groin area.
b. Minor discomfort from sitting in a chair for up to 120 minutes.
c. It is not known but it is unlikely that there may be increased risk of bleeding or wound healing at the surgical site.
There may or may not be a direct benefit to you from these procedures. The investigator, however, may learn more about methods to minimize effect of surgery on urinary incontinence and sexual dysfunction from this study.
Participation is voluntary and the only alternative is to not participate. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions or concerns about this study, you may contact Dr Raj Rajasekaran at the San Diego VA Healthcare System at (858)-552-8585 x 7114. In the event of illness or injury that you believe to be related to the study, or have questions about this research, you can call Dr. Sakamoto at (858) 552-3407 during the day, or you can call the page operator at (858)552-8585

after 5:00 PM and ask that they page Dr. Sakamoto. If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at (858) 642-3817, VA Research Service at (858) 642-3657, VA Regional Counsel at (858) 642-1540, or the VASDHS Human Research Protection Program at (858) 642-6320.

RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

Dr. Rajasekaran, Dr. Sakamoto and their associates are conducting a research study to reduce and/or prevent the leakage of urine after prostate surgery and possibly to prevent sexual dysfunction caused by surgery and are asking for your consent to this research. This study is sponsored by VA Central Office.
You have been asked to participate because you are enrolled for prostate surgery, which is associated with a high chance of incontinence and sexual dysfunction. There will be approximately 20 participants at this VA site.
This study is being performed to understand if pulsating magnetic field will help in strengthening the pelvic region's muscles and if this strengthen will result in improvement in sexual function and/or urinary incontinence that you have.

FOR HOW LONG WILL I BE IN THE STUDY?

Your participation will take approximately 1 to 1.5 hours each time you come to the VA hospital, and you will be expected to come to the hospital 12 times over a three-month period. Each subject will participate for a total of 6 months, but the entire study duration will be two years.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

You will be assigned into one of two groups: treatment or non-treatment. Your chances of being assigned to either the non-treatment or treatment group are equal, just like flipping a coin. If you agree to be in the study, the following will happen to you at the San Diego VA Healthcare System in the Urology Service (independent of the group- no treatment or treatment group):

- In first week 4, 8 and 13, you will complete a urinary symptom and sexual function questionnaires. If you have concerns or are uncomfortable with any questions you may skip those (Please remember, these questions will help the investigators with the effectiveness of the treatment). These questions relate to your symptoms regarding sexual function and urinary incontinence (urine leakage).
- You will undergo MR imaging (only first and week 13 visit).

- From first visit onwards, you will be positioned on a chair (all sessions) twice a week for twelve weeks.
- Blood flow measurement in the groin area (only during the first, week 4, 8, 12 and 13 sessions). Two devices will be used for this purpose, an ultrasound machine and a Laser device.
- For magnetic stimulation you will be seated in a chair with a magnet placed below the seat. The magnet will be pulsed and the muscles in the groin area will be activated to provide exercise to the muscles in that area (if you are in the no treatment group you will not be exposed to the magnetic treatment, though we will turn on the machine. In the no treatment group, the device will be set up in a similar way as in the treatment group but no effective energy will be delivered).
- The entire procedure will be completed in less than 1.5 hours.
- After completion of these procedures, you will be free to go home.
- If you are unable to keep a scheduled appointment, please contact Dr Raj Rajasekaran at (858)-552-8585 x 7114 to reschedule your appointment.
- Please check with Dr Raj Rajasekaran if you wish to participate simultaneously in any other clinical study before enrolling.

Magnetic stimulation technique has been successfully used for many other medical procedures with no adverse effects.

WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?

All the elements listed above are research related, none of these are performed for routine clinical purpose.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Participation in this study may involve some added discomforts. The procedures used are likely to cause:
a. Minor discomfort from using the magnetic probe. This may cause some tingling sensation in the groin area.
b. Minor discomfort from sitting in a chair for up to 120 minutes.
d. It is not known but it is unlikely that there may be increased risk of bleeding or wound healing at the surgical site.
This device has been used clinically (pain treatment and PTSD) with no adverse effects, discomfort or pain.
MRI: Some people experience a 'closed-in' feeling due to the relatively restricted space within the MRI machine. You may not be able to have the MRI procedure if you have certain metal, surgical clips, or implants, including a brain aneurysm clip or a pacemaker, in your body or tattoos because during the MRI procedure metal can heat up and move, or clips and implants

stop working. Dental fillings are not a problem. If there is any question about whether there is metal in your body, you may be requested to have an X-ray to determine this; the X-ray will become part of your medical record. You will need to remove all jewelry or clothing with metal before having the MRI. All these precautions will be reviewed with you immediately before you have the MRI.
The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may or may not be a direct benefit to you from these procedures. The investigator, however, may learn more about methods to minimize effect of surgery on urinary incontinence and sexual dysfunction from this study.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS RESEARCH STUDY?

Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution. There are no alternatives to this study other than to follow the standard pelvic muscle exercises as suggested to you by your urologist.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

In the event of illness or injury that you believe to be related to the study, or have questions about this research, you can call Dr. Sakamoto at (858) 552-3407 during the day, or you can call the page operator at (858)552-8585 after 5:00 PM and ask that they page Dr. Sakamoto. If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at (858) 642-3817, VA Research Service at (858) 642-3657, VA Regional Counsel at (858) 642-1540, or the VASDHS Human Research Protection Program at (858) 642-6320.
The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance, but no additional compensation is available.

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued

participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The investigator might terminate participation of a participant, for not willing or unable to complete the study protocol. In case the urologist feels there may be increased risk of bleeding at the surgical site the participation may be terminated.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact the Principal Investigator, Dr Raj Rajasekaran at (858) 552-8585 x7114 or by email at mrajasek@ucsd.edu.
Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.
Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

You will be compensated for each visit for the transportation cost up to a maximum per visit of $10.00. No other compensation will be provided for this study.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

If you have study related questions or concerns you can contact Dr Raj Rajasekaran at (858)-552-8585 x7114,

FUTURE USE OF DATA AND RE-CONTACT

If we conduct a follow-up study for the same medical issues, would you be willing to participate? If you do please let us know how we may contact you, by phone or email?

☐ Yes, I may be contacted for future research opportunities as described. _____ (initial)

☐ No, I do not wish to be contacted for future research opportunities as described. _____ (initial)

☐ Phone _____ ☐ Email address_____

HOW WILL MY PRIVATE INFORMTION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall.

All data will be analyzed at the San Diego VA Hospital.

No data will be taken out of the VA Hospital facility.

Any presentations or publications from this information will not identify you.

We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, the Food and Drug Administration, and federal compliance officers may look at or copy portions of records that identify you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

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Principal Investigator: M. Raj Rajasekaran, PhD

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Dr. Raj Rajasekaran or Dr. Sakamoto has explained the study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. *Include if applicable:* A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.

_____ _____

Participant's Signature Date

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information learned from the procedures described in this consent form. The researchers may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results.

The research team may also need to share your health information and the information it collects to other entities as part of the study progress. You also give your permission for the research team to disclose your information to the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, the Food and Drug Administration, and federal compliance officers may look at or copy portions of records that identify you.

Your health information disclosed outside the VA as described in this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address: Dr Raj Rajasekaran, Research (111), San Diego VA Healthcare System, 3350 La Jolla Village Drive, San Diego CA 92161.

If you revoke this authorization, Dr Raj Rajasekaran and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

While this study is being conducted you will have access to your research-related health records.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization.

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'Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire on Jan 1, 2026.

AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

By signing this document below, I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this document. This authorization has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint. I will be given a signed copy of this document for my records. A copy of this signed document will also be put in my medical record.

_____ _____ _____

Participant's Signature Last 4 of SSN Date

A copy of this document will be provided to the research participant.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research.
You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as a research subject, please contact the VASDHS Research Compliance Officer at (858) 642-3817 or RCO@vapop.ucsd.edu. You may leave an anonymous comment at the VASDHS research compliance hotline at 858-642-6311.

REF: California HSC 24170-24179.5

A copy of this document will be provided to the research participant.