Are you participating in any other research studies? _____ Yes _____No

**Project Summary:**

- Consent is being sought for research and participation is voluntary.
- The prostatic artery embolization (PAE) procedure is being studied to determine if the procedure can be helpful for patients with prostate cancer and lower urinary tract symptoms (LUTS).
- The PAE procedure uses Embospheres Microspheres, a tiny particle about the size of grain of sand made of a type of gelatin, which has been cleared by the FDA for the PAE procedure.
- The PAE procedure is an approved treatment for benign prostatic hypertrophy (BPH). The procedure reduces the size of the prostate and improves symptoms caused by an enlarged prostate. Many patients with prostate cancer may also suffer from symptoms of enlarged prostates.
- Participants will undergo the PAE procedure and follow-up consisting of clinic visits at 2, 6, and 12 months after treatment. Patients are required to follow-up at Stanford Medical Center for imaging.
- Magnetic resonance (MRI) scans of the pelvis will be required before and after the procedure. Labwork and urine flow studies will also be performed.
- Complications of the procedure may include painful and frequent urination, blood in the urine and semen, infection, pelvic pain, groin swelling, and sexual dysfunction. Rare severe complications include damage to the rectum, bladder, and penis. It is unknown if the procedure will affect the prostate cancer.
- Benefits include improvement in lower urinary tract symptoms with a low-risk outpatient procedure that may avoid surgery.
- Alternative treatments include: medical management, minimally invasive surgeries (laser, Urolift, Rezum), and surgery (transurethral resection of the prostate (TURP), prostatectomy.

## PURPOSE OF RESEARCH

You are invited to participate in a research study of prostatic artery embolization (PAE). We hope to learn if the PAE procedure can improve symptoms in patients with enlarged prostates and prostate cancer. You were selected as a possible participant in this study because your symptoms may be improved with the PAE procedure while you are undergoing treatment for prostate cancer.

If you decide to terminate your participation in this study you should notify Dr. Picel at 650-736-9081.

This research study is looking for 10 patients with benign prostatic hyperplasia (BPH) undergoing radiation treatment for prostate cancer. All study activities will take place at Stanford University.

## VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

## DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 2 years. You will undergo an initial evaluation in Interventional Radiology and Urology clinic. A separate visit will be required for the procedure itself and for follow-up visits 2, 6 , and 12 months after the procedure.

## PROCEDURES

If you choose to participate, Dr. Picel and his research study staff will describe the procedure and required follow-up visits and complete this written informed consent document.

If you are coming in-person to research visits, you are required to be fully vaccinated—2 doses (1 for Johnson and Johnson), 2 weeks out and to provide

proof of your vaccination (e.g., CDC COVID-19 Vaccination Card, e-Health record, etc.) to the researcher prior to study participation. Alternately, you can provide a negative COVID test within 72 hours of your visit.

You will undergo the following:

Visit 1. Screening visit/baseline:

- Written informed consent
- Medical history
- Physical exam, including vital signs
- Recording of medical conditions and medications
- Complete BPH symptom scores
- Ultrasound of your prostate
- Assessment of your urine flow in clinic
- Blood draw and urine collection for laboratory testing
- If needed, arrangement of prostate biopsy to evaluate for prostate cancer
- Preprocedural pelvic MRI with prostate volume measurement

Visit 2: Prostatic artery embolization (PAE):

- IV placement for medication and conscious sedation.
- Enter the blood vessels from the right groin.
- Enter the internal iliac arteries and perform arteriograms to identify the prostatic arteries.
- Enter the prostatic arteries and perform arteriograms.
- If needed connections to other pelvic vessels will be closed off with metallic coils. If other vessels cannot be closed off, the procedure may be performed only on one side of the prostate. If other vessels affect both sides of the prostate, no embolization will be performed.
- Embolization is performed with Embosphere Microspheres, which are tiny round particles that block the blood flow of an artery.
- A vascular closure device is used for the femoral artery site.

- You will be discharged home approximately 6 hours after the procedure.

Visit 3. 2 month follow-up visit (± 2 weeks):

- Recording of medications
- Complete BPH symptom scores
- Blood draw for prostate-specific antigen (PSA) laboratory test
- Assessment of your urine flow in clinic
- MRI of your pelvis with and without contrast
- Adverse event screening form

Visit 4. 6 month follow-up visit (± 4 weeks):

- Physical exam, including vital signs
- Recording of medications
- Complete BPH symptom scores
- Ultrasound of your prostate
- Blood draw for prostate-specific antigen (PSA) lab test
- Assessment of your urine flow in clinic
- Adverse event screening form

Visit 5. 12 month follow-up visit (± 4 weeks):

- Physical exam, including vital signs
- Recording of medications
- Complete BPH symptom scores
- Ultrasound of your prostate
- Assessment of your urine flow in clinic
- Adverse event screening form

The PAE procedure and the follow-up MRI scan performed during visit 3 are being performed as part of this study. The procedure takes approximately 4 hours. The MRI study obtained before the procedure is used to measure the prostate size and identify the pelvic arteries before the treatment. The MRI scan

performed after 2 months is to measure the prostate size and evaluate the effects of the procedure on the prostate. The labwork and clinic visits are standard for the evaluation of patients with BPH and not considered experimental.

Lab tests are obtained before the procedure, 2 and 6 months after the procedure. The lab tests include: complete blood count, basic metabolic panel, international normalized ratio (how thin the blood is), and prostate-specific antigen. Approximately 3 tablespoons of blood are drawn for these tests. A urine sample is also collected before the procedure. All samples are tested at Stanford hospital. Samples are not saved for future research.

MRI (Magnetic Resonance Imaging):

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. During the scan you will be asked to lie on a long narrow couch for a certain amount of time, about 60 minutes, while the machine gathers information. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken steps to relieve the "claustrophobic" feeling.

Risks:

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed, so it is very important that you notify the operator. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of

head or eye injury involving metal fragments, or if you have ever worked in a metal shop, you should notify the operator/investigator. You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs. There is also a possibility of tinnitus (ringing in the ears) after the MRI.

If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator. If you have kidney problems, please tell the operator.

It has been observed that deposits of Gadolinium-based contrast agent (GBCA) remain in the brains of some people who undergo four or more contrast enhanced MRI scans, long after the last administration. It is not yet known whether these Gadolinium deposits are harmful or can lead to adverse health effects. You should talk to the study doctor if you have any questions about the use of GBCAs with MRIs.

**IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME**

## PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.

- Tell the Protocol Director or research staff if you change your mind about staying in the study.

## WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Picel at 650-736-9081.

If you withdraw from the study:

- You may be asked to complete follow-up clinical evaluations in the 12 month visit

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- You are unable to attend follow-up visits or provide follow-up information during a phone visit.

## POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

Participation in this study may involve some added risks or discomforts. These include the following:

1. Blood stream or urinary tract infection.
2. Painful urination, frequent urination, or blood in urine.
3. Sudden inability to pass urine.
4. Blood in semen and rectal bleeding.

5. Blood vessel blockage or injury resulting in acute pain or tissue injury that could result in the need for amputation.
6. Damage to pelvic organs.
7. Pelvic pain.
8. Contrast reaction and drug allergy.
9. Damage to kidneys requiring dialysis.
10. Radiation skin injury.
11. Inability to treat the prostate and improve symptoms. Need for multiple procedures.
12. Rare severe pelvic organ damage could require surgery or result in permanent organ damage.
13. Complications of the procedure could rarely lead to prolonged hospitalization and death.
14. Worsening prostate cancer.
15. Sexual dysfunction.
16. Loss of confidentiality.
17. Fever, low or high blood pressure.
18. Groin swelling, bruising, or blood vessel injury.
19. Reaction/allergy to medications used during the procedure, including sedation risks (nausea, headache, restlessness, diarrhea, passing out, low blood pressure, slow or inadequate breathing, airway obstruction, slow heart rate, confusion, agitation, blurred vision, stroke, and chest pain).
20. Death.

The dose to your skin will be about 7685 mGy. This dose may result in temporary or permanent hair loss and possible skin changes or damage.

You will be exposed to radiation during this research from a Fluoroscopic exam. Your radiation exposure will be about 124.1 mSv. This amount of radiation has an estimated risk of fatal cancer of about 0.7%. If randomly selected members of the general population were exposed to the radiation exposure from this research, the extra lifetime risk of dying from fatal cancer may be about 7 in

1,000. Statistics represent averages and do not predict what is going to happen to you. They do not take into consideration individual risk factors including lifestyle (smoking, diet, exercise, etc), family history (genetics) or radiation exposure. The majority of cancers occur later in life and the average lifetime risk of dying from cancer is 25% (1 in 4). The principal investigator for this research study has determined and verified that some of the x-rays and/or imaging scans prescribed for this study would typically be performed as part of the standard medical care required to adequately monitor your current illness. If you are especially concerned with radiation exposure, or you have had a lot of x-rays or imaging scans already, you should discuss this with the principal investigator for this study, Dr. Picel, or your regular doctor.

Participants are required to travel to Stanford Medical Center for testing, which may inconvenient due to time and cost of travel.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

## POTENTIAL BENEFITS

The embolization procedure has been shown to decrease the prostate size and help improve the symptoms caused by BPH. We hope that the majority of participants will experience improved symptoms from this procedure based on prior investigations. The degree of improvement and duration of effects in patients with prostate cancer is unknown at this time.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

## ALTERNATIVES

The alternatives to participation in this study are continued medical care or surgical treatments for BPH provided by a Urologist. This may include taking medications or performing surgery. Surgeries performed for this condition include transurethral resection of the prostate (TURP), needle ablation, laser ablation techniques, Urolift, and Rezum procedures. These are standard treatments for patients with BPH. Important risks and benefits of these

alternative treatments will be explained in detail by your Urologist before treatment in the study.

If you choose not to participate, you can discuss these treatments with your Urologist. If you participate in the study, these treatments may still available for you if your symptoms are not improved.

## PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

## ClinicalTrials.gov

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.

## CONFIDENTIALITY

Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Your specimens will not be used or distributed for future research studies even if all identifying information is removed.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as

required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain information on the safety and effectiveness of the PAE procedure using Embosphere microspheres in participants with enlarged prostates and prostate cancer; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

# Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

## What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of the study is to evaluate the safety and efficacy of prostatic artery embolization (PAE) to reduce the symptoms of lower urinary tract symptoms (LUTS) in patients with prostate cancer undergoing radiation therapy. State and federal privacy laws protect the use and release of your health information. Your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that your information can be shared with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form.

## Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment.

Signing the form is not a condition for receiving any medical care outside the study.

## If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Dr. Andrew Picel
Stanford University Department of Radiology
300 Pasteur Drive
Stanford, CA 94305

## What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including all records pertaining to evaluation and treatment of benign prostatic hyperplasia. This includes, but is not limited to, progress reports, clinic visits, hospital visits, Emergency Room visits, laboratory tests, pathology reports, operative reports, and imaging studies. Numbers

*IRB Use Only*
Approval Date: May 10, 2022
Expiration Date: May 10, 2023

and codes that will identify you, such as your medical record number, initials, and date of birth.

## Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Andrew Picel
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

## Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Researchers to improve the design of future studies or to gain approval for new drugs or healthcare products.
- Food and Drug Administration

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

## When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

## Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

_____ _____

Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____

Print Name of LAR

_____

LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

## FINANCIAL CONSIDERATIONS

Payment/Reimbursement

You will not be paid to participate in this research study.

Costs

If you participate in this study, services, supplies, procedures, and care associated with the study are billed to you and your insurance. There may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Consultative or Financial Relationships

Dr. Andrew Picel receives no direct compensation for this study. This is an unsponsored research study.

## COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

## CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Picel. You may contact him now or later at 650-736-9081.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Picel at 650-736-9081.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact Stanford Interventional Radiology at 650-736-9081.

## EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;

- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

_____ _____

Signature of Legally Authorized Representative (LAR) (e.g., parent, guardian or conservator) Date

_____

Print Name of LAR

_____

LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness
*(e.g., staff, translator/interpreter, family member)*

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form ("summary form"):*

*Must be signed by the witness AND the Person Obtaining Consent (POC).*

*The non-English speaking participant/LAR does not sign the English consent.*

*The non-English speaking participant/LAR should not sign the HIPAA participant line*

*if the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*