UNIVERSITY OF MINNESOTA

RESEARCH SUBJECT CONSENT FORM

Title:	**Prostate Artery Embolization (PAE) for Lower Urinary Tracts Symptoms (LUTS) due to Benign Prostatic Hyperplasia (BPH)**
Principal Investigator:	**Jafar Golzarian, M.D., Phone (612) 625-5147** **Department of Radiology** **University of Minnesota**
Sub Investigators:	**Shamar Young, M.D., Phone (352) 219-3604** **Department of Radiology** **University of Minnesota**
	Michael Rosenberg, M.D., Phone (612) 626-5388 **Department of Radiology** **University of Minnesota**
	Prashant Shrestha, M.D., Phone (612) 626-5589 **Department of Radiology** **University of Minnesota**

You are being asked to participate in a clinical research study. You are being asked to take part in this study because you have been diagnosed with benign prostatic hyperplasia (BPH) that has not been responsive to medications. BPH is an enlargement of the prostate gland which causes the tube that carries urine from your bladder outside of your body to become narrow. In most cases it can be treated with medications, but close to 10% of men who develop an enlarged prostate surgery is needed to correct the symptoms from this disorder. This study will test a new method of treating the blood vessels that flow to the prostate with the hope that subjects who have BPH will have relief of symptoms. Clinical studies only include people who choose to take part. These people are referred to a research subjects. Your participation is voluntary which means you can choose whether or not to participate.

The purpose of this consent form is to give you information about the research study. This form describes the purpose, procedures, benefits, risks, discomforts and safety measures of the research study. Please ask the study doctor or the study staff to explain any words or facts that you do not understand. You may wish to discuss this study with your family and friends before making your decision. .

This study is being has been designed and will be conducted by Dr. Jafar Golzarian along with his colleagues from the Department of Radiology at the University of Minnesota. We hope to enroll approximately 50 patients at the University of Minnesota.

Why is this study being done?
Currently the standard treatment for BPH involves either medical therapy or surgery, neither of which is a solution for all patients. These therapies and procedures can have side effects, varied recovery times and the possibility of not relieving the symptoms of BPH. This research study is intended to help develop a less invasive, safer, and easier to tolerate treatment for men with this condition.

The study doctor and his team believe that by cutting off blood flow to the prostate using microscopic beads through a targeted injection will to lead the reduction in the swelling of the tissue surrounding the prostate. By reducing this swelling, subjects will experience relief of their symptoms from this condition. The use of microscopic beads has been approved by the Food and Drug Administration (FDA) for other clinical uses, but it has not been cleared for this procedure.

How long will the study last?
Your participation in this study will last up to one year.

What is involved in this study?
Should you agree to participate in this study, you will be asked to complete a screening visit, undergo the microscopic bead injection and complete four study visits after the injection. These visits will happen approximately every 3 months. A scheduled of these events are detailed below:

	Pre-Bead Injection	Study Treatment	1 Month	3 Months	6 Months	12 Months
Labs	X			X		
**Anoscopy	X			X		
**Cystoscopy	X		X			
Uroflowmetry	X		X	X		X
Questionnaires	X		X	X	X	X
Microscopic Bead Injection		X				
Imaging of Treatment Site	X			X		
Adverse Event Assessment	X	X	X	X	X	X
Review Medical History	X		X	X	X	X
Pain Questionnaires			X	X	X	X

** These tests may be performed sooner or more often should your test results show irregularities after having the embolization procedure.

Risks of Study Participation

Cystoscopy: is a test that is performed by inserting a small camera into the body in order to examine a person's bladder, urinary tract and prostate.

- Rarely, this procedure can introduce germs into your body, causing an infection.
- You might experience temporary abdominal pain and a burning sensation when urinating after this procedure.
- This procedure might cause some blood in your urine.

Uroflowmetry: is a test that measures the flow and strength of your urine stream during while emptying your bladder. Some conditions may interfere with the accuracy of this test. These factors include, but are not limited to, the following:

- Straining with urination
- Body movement during urination
- Certain medications that affect bladder and sphincter muscle tone

Prostate Artery Embolization: is a procedure where a trained doctor will inject microscopic beads into the blood vessel that supplies blood to the prostate artery.

- Arterial injury at puncture site or to the arteries in the pelvis, tenderness of swelling of artery entry site
- Injury to the skin from the X-rays used
- Cardiac or respiratory problem caused by sedation
- Burning with urination, urinary infection
- Pain or swelling in the penis
- Blood in the urine or with ejaculation
- Blood in the stool, injury to the rectum
- Bladder injury
- Future fertility problems
- Allergic reaction to material injected to block the arteries or contrast dye used in the procedure.
- Injury to kidneys from the contrast material
- Death

Radiation Exposure:

As part of this study you will undergo a procedure that involves exposure to ionizing radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The average amount of radiation that the average person would receive from this procedure is approximately 10 times that received from natural sources of radiation by a Minnesota resident in one year (3 mSv). This exposure involves minimal risk and is necessary to obtain the research information desired.

Benefits of Study Participation

There is no guarantee that there will be any direct benefit to you from study participation.

You may experience a reduction in the swelling in your prostate because of participating in this study. The information collected in this study may be used to help others with this condition in the future.

Alternatives to Study Participation
You may decide for any reason not to join this study. You do not have to participate in this study to get treatment for your condition. Other treatments are currently available to reduce the swelling of your prostate. Your study doctor will talk to you about your choices for treatment along with the risks and benefits of each one.

Study Costs/Compensation
All procedures that are required only for this study and that are not part of your regular medical care will be provided to you at no charge. You or your health insurance will need to pay for medications and clinic, hospital, and doctors' services that are part of your regular medical care.

Research Related Injury
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Confidentiality
The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be reviewed by regulatory authorities including the Food and Drug Administration (FDA), study monitor, auditors and by departments at the University with appropriate regulatory oversight. Your information may also be transmitted and/or reviewed by University of Minnesota (UMN), University of Minnesota Physicians (UMP) and University of Minnesota Medical Center, Fairview personnel who monitor research and UMN, UMP and Medical Center personnel who need access to the information to complete the clinical study. These organizations and people must keep the information private as required by law. Study data will be encrypted according to current University policy for protection of confidentiality.

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 could identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Protected Health Information (PHI)
Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. You will be asked to review and sign a separate HIPAA authorization concerning the use of this information. To these extents, confidentiality is not absolute.

Voluntary Nature of the Study
Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota or the University of Minnesota Medical Center, Fairview. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researcher conducting this study is Dr. Jafar Golzarian. You may ask any questions you have now, or if you have questions later, you are encouraged to contact them at 612-626-5388.

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participant/questions-concerns. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

After the study, you might be asked to complete a survey about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey after the study is over, but you would like to share feedback, please contact the study team or the Human Research Protection Program (HRPP). HRPP can be contacted at 612-625-1650 or go to www.irb.umn.edu/report.html.

You will be given a copy of this form to keep for your record.

Statement of Consent
I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

*Printed Name of Subject:*_____

*Signature of Subject:*_____

Date: _____

Printed Name of
Person Obtaining Consent: _____

Signature of
Person Obtaining Consent: _____

Date: _____