The Ohio State University Consent to Participate in Research

Study Title:	**Radiographic and Clinical Outcomes Following Unilateral or Bilateral Posterior Fixation in Minimally Invasive Transforaminal Lumbar Interbody Fusions**
Principal Investigator:	**H. Francis Farhadi, MD, PhD**
Sponsor:	**OSU**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

You are being asked to take part in this study because you are between 18 and 80 years old and have problems with the bones in your lower back (lumbar disease). Cautious management over at least 3 months has not brought relief from your back and/or leg pain. You are scheduled to undergo surgery to treat your lumbar disease. The surgery will be followed by placement of screws in the back of the bones of your lower back. This includes placing solid metal rods that are connected and secured to adjacent vertebrae (bones of the back) using screws. The screws are used to hold the spine together. Everyone who takes part in this study will be assigned to one of the following 3 study groups: 1) One-sided screw placement into the bones above and below the area where the nerve is being surgically relieved of its pinching; 2) Same as group 1 but with an

additional stand alone screw which crosses the spinal joint placed into the joint on the other side; 3) Screw placement on both sides into the bones above and below the area where the nerve is being surgically relieved of its pinching.

The purpose of this study is to compare the healing of your spine at 24-months following surgery and screw placement among the 3 groups. Your doctor will also compare your clinical outcomes (i.e. how you are feeling and how you are able to do your usual daily activities) and your immediate and delayed medical and surgical complications among the 3 study groups. The goal of this study is to determine if treating patients with one of the 3 groups is better than the others.

The surgery and the screw placement are considered standard of care treatment and are FDA approved treatments for patients with lumbar disease. We do not know which, if any, of the 3 ways to do this are better than any of the others.

2. How many people will take part in this study?

Up to 114 patients will take part in this study at OSU. Approximately 38 patients per group will be enrolled in the study.

3. What will happen if I take part in this study?

If you decide to be a part of this study, you will be randomly (by chance, like a coin flip) assigned to one of the following 3 groups:

Group 1: One-sided screw placement into the bones above and below the area where the nerve is being surgically relieved of its pinching
Group 2: Identical to group 1 but with an additional stand alone screw which crosses the spinal joint placed into the joint on the other side
Group 3: Screw placement on both sides into the bones above and below the area where the nerve is being surgically relieved of its pinching

You will have an even chance of being placed in any of the groups. Everyone in all of the groups will first undergo a preoperative lumbar MRI, lumbar CT scan, and lumbar x-rays, medical evaluations, and history and physical examinations and then will undergo the minimally invasive transforminal lumbar interbody fusion (MI-TLIF) surgery. This procedure is considered standard of care for the treatment for your condition. The surgery will include the screw fixation technique specific for the group into which you have been assigned. The procedure to place screws in the back of the bones of your lower back is also considered standard of care for treatment of your condition.

If you qualify and decide to participate in the study, your participation will last approximately 24 months and will include up to 7 visits to the doctor's office and hospital.

Visit #1: Screening and Enrollment (prior to surgery)
Visit #2: Surgery
Visit #3: 6 week post- surgery follow-up
Visit #4: 3 month post- surgery follow-up
Visit #5: 6 month post-surgery follow-up **
Visit #6: 12 month post-surgery follow-up
Visit #7: 24 month post surgery follow-up
Visits at 6 and 12 months are optional and can be completed via phone instead.

You will be required to return to your doctor's office for these planned follow-up visits except as noted above. You will be asked to complete questionnaires that will give us information about your general health, symptoms related to your lumbar disease, and how your lumbar disease is affecting your everyday life. You will complete the questionnaires at every visit except for your 6 week follow-up visit. It may take approximately 10-15 minutes to complete the questionnaires each time. **Please note that if you are not comfortable with any question you may refuse to answer it.** Your physician will also fill out a questionnaire about your progress and will perform clinical examinations.

Women of childbearing potential will undergo a serum pregnancy test prior to enrollment in the study to confirm that they are not pregnant. This is considered a standard of care test.

As mentioned above, you will undergo a pre-study lumbar MRI, lumbar CT, and lumbar x-ray. The lumbar x-ray will also be done at the 6 week, 3 month, 12 month, and 24 month follow-up visits. You will also undergo a lumbar CT scan at the 12 month follow up visit. These procedures are all considered standard of care tests.

For detailed schedule, please see table below:

	Pre-Study	6 wk. F/U	3 mo. F/U	6 mo. F/U	12 mo F/U	24 mo F/U
Test and Observations						
History &Physical	X	X	X	X[a]	X[a]	X
Height	X	X	X	X[a]	X[a]	X
Weight	X	X	X	X[a]	X[a]	X
Vital Signs	X	X	X	X[a]	X[a]	X
Serum Pregnancy Test	X					
Consent	X					
Procedures						
Lumbar MRI	X					
Lumbar CT	X				X	
Lumbar X-Rays	X	X	X		X	X
Surgical Outcome Measures						
Questionnaires	X		X	X	X	X

a. Optional

4. How long will I be in the study?

You will be enrolled in the study for 2 years. You will undergo MI-TLIF surgery followed by the screw instrumentation according to the group into which you were randomized. Data about you will be collected before, during and after your surgery. You will be required to complete follow-up at 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery. A lumbar CT scan will occur at the 12-month visit. Your participation in the study will be over after the 24 month follow-up visit.

5. Can I stop being in the study?

Taking part in this research study is voluntary. You may leave the study at any time. You may do so by sending a letter to or calling or e-mailing the study Principal Investigator, Dr. Francis Farhadi:

Francis Farhadi, MD, PhD
N1025 Doan Hall
410 West 10th Ave.
Columbus, OH 43210
Phone #: 614-366-4961
E-mail address: Francis. Farhadi@osumc.edu

If you decide to leave the study all of your information that has been collected to the point of withdrawal will be used.

If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Your physician may take you out of the study, even without your agreement, if:

- It is not in your best medical interests to continue.
- You do not follow instructions.
- The study is terminated.

However, for your safety, if you leave the study early, your study doctor or his staff may or may not ask you to finish the study termination procedures.

6. What risks, side effects or discomforts can I expect from being in the study?

This surgery is standard of care and will be performed regardless of your participation in this study. Standard of care is how most people with your disease or condition are surgically treated. You may have risks of surgery whether you take part in this study or not. The risks associated with the surgery will be described to you separately as this consent form pertains only to this research study.

You may have a number of x-rays and MRI scans that are part of the regular care for your condition, and you would have them whether or not you participate in this research. These studies will not add to the risk of the research. However, if you have concerns about the overall radiation exposure or MRI safety issues, you should discuss them with your physician.

A possible health problem seen with radiation exposure is the development of cancer later in life. This extra cancer risk is higher at younger ages and for girls and women. The extra lifetime risk of dying of a fatal cancer due to the radiation exposure during your follow up period may range from about one in 3,000 to about one in 1,000. At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all.

We can compare this possible extra cancer risk to other risks (over a lifetime) that everyone is subject to in everyday life. For example, the chances of a person dying of cancer with no extra radiation exposure are about one in 4. The chances of dying in a car crash are about one in 82, and the chances of being killed by a car while crossing the street are about one in 730.

The only other risk associated with this study is a breach (break) of confidentiality. Such a breach of confidentiality would only occur in the event of an error as all paper and

computer based files will be kept in a secure location and only be accessible to personnel involved in the study. Efforts will be made to keep personal information confidential, but the researchers cannot guarantee absolute confidentiality.

There may be side effects and discomforts that are not yet known.

Other points to consider:
You may refuse to do any of the study tasks that you do not wish to.

You have the right to refuse to answer any question for any reason.

Pregnancy/Childbearing Potential
If you are a female and plan to become pregnant during the expected course of the study, are currently pregnant, or are breast- feeding, you must not take part in this study due to CT scans and MRI. A pregnancy test will be done if you are a female and able to bear children. This is the standard of care. All women of childbearing age are tested for pregnancy prior to the surgical procedure. You must use an acceptable method of birth control. If you decide to take part in the study and think you have become pregnant within 3 months after surgery, tell the study doctor. The physician may remove you from the study due to the X-Rays and CT Scans; however your pregnancy and the birth of your child may be monitored for safety.

7. What benefits can I expect from being in the study?

There will be no direct benefits to you during this study. However, the results from this study may help us learn more about treating patients with degenerative lumbar spine disease in the future. Researchers hope to find out from this study if participants may benefit from receiving one type of screw instrumentation over another as this is not currently known at this time.

8. What other choices do I have if I do not take part in the study?

You may still be able to undergo MI-TLIF with pedicle screw instrumentation if you choose to not participate in this study because these treatments are considered standard of care. You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Paper based files will be kept in a secure location in the OSU Department of Neurological Surgery research office and only accessible to personnel involved in the study. Within the research office, the research records are kept in a locked drawer or file cabinet. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. If the information obtained from this study is published in a medical journal, you will not be identified by name.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on 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.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

All of the tests (CT scan), procedures (surgery), and devices are considered part of your standard medical care (not part of the research.) All of these standard of care tests and procedures will be charged to you or your insurance company. You will be responsible for meeting any co-pay and deductible requirements by your insurance plan.

Participating in this research study may lead to additional costs to you. In some cases, it is possible that your insurance company will not pay for the standard of care procedures including the surgery as a result of your participation in the study.

11. Will I be paid for taking part in this study?

You will not be paid for participating in this study.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **Dr. H. Francis Farhadi at 614-366-4961**.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. H. Francis Farhadi at 614-366-4961**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time