Study Title: **Lumbar Fusion with 3D-Printed Porous Titanium Interbody Cages – A Single-Blinded Randomized Controlled Trial Evaluating NexxtMatrixx™ Versus PEEK Cages**

Principal Investigator: **Andrew Grossbach, MD**

Sponsor: **NexxtSpine**

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Document: **Informed Consent Form and HIPAA Research Authorization (Combined)**

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

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- **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?

Lumbar interbody fusion is a surgery done to stabilize the spine while helping with bone growth. When a patient undergoes a lumbar interbody fusion procedure, a cage is placed into the space in the spine to help bone grow and to keep the spine aligned. This cage may be made out of a material named Poly-ether-ether-ketone (PEEK) or titanium. Two devices that can be used for this procedure are the NexxtMatrix™ titanium cage and the Honour™ PEEK cage.

This study is being done to see how safe and effective the NexxtMatrix™ titanium cage and the Honour™ PEEK cage are when they are used in lumbar interbody fusion procedures.

You are being asked to participate in this study because you will be having a lumbar interbody fusion procedure.

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

It is expected that about 70 patients will take part in this study.

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

If you agree to take part in this study, you will be randomly assigned (like flipping a coin) to receive either the NexxtMatrix™ titanium cage or the Honour™ PEEK cage during your lumbar interbody fusion procedure. You will not be able to choose which device you receive and you will have a 1 in 2 (or 50%) chance of receiving each device.

Before your surgery, you will have a physical exam and an assessment of your pain. You will also complete a urine pregnancy test if you are able to become pregnant.

After your surgery, you will be asked to return for follow-up visits. These visits will occur 3 months, 6 months, and 12 months after your surgery. You or your doctor may request an additional follow up at 2 years post-surgery. The study team will collect any data up until your final visit. During these visits you will complete a physical exam and an assessment of your pain. At each of these visits you will have x-rays of your back done as well. At the 6 month visit, you will also complete a computerized tomography (CT) scan of your back. A CT scan is an X-ray procedure where a high-speed computer is used to make multiple images or pictures of your body. You will be asked to lie still on a table and at time may have to hold your breath for a few seconds in order to avoid blurring the pictures.

All of these procedures are considered standard of care, which means that they would be done even if you were not participating in this study. A CT scan post-op is standard of care in clinical practice to document healing. The CT scan will be done at 6 months post-surgery rather than the usual 12 months post-surgery.

The study team will access your medical records while you are in the study to obtain information about your medical history, demographic information, physical exams, procedures, medications and treatments, and surgery.

4. How long will I be in the study?

You will be in the study for up to 24 months after your surgery. Each visit will take approximately 30 minutes.

5. Can I stop being in the study?

You may leave the study at any time. 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.

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

Loss of confidentiality:
There is a potential risk to your privacy. Every effort will be made to maintain your privacy, however this cannot be guaranteed.

Risks of Lumbar Interbody Fusion Surgery:
The risks of the surgery include infection, nerve damage, blood clots, blood loss, bowel and bladder problems, and complications associated with anesthesia. It is also possible that the bone and graft will not properly fuse. If this occurs, additional surgery may be required. The risks of the surgery are the same whether you receive the NexxtMatrix titanium cage or the Honour PEEK cage.

Radiation Risks:
If you take part in this research, you will have medical imaging studies. The tests or treatments you will have include a lumbar spine CT scan. This test involves a small amount of radiation. The radiation dose from this research is about 6 millisievert. To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone received a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 2 extra years' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only, and does not include any exposure you may have received or will receive from other tests.

A possible health problem seen with radiation exposure is the development of a second 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 from this research may range from about one in 6,000 to about one in 2,000. 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.

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

You may or may not benefit from participating in this study.

Your participation in this research may help other patients undergoing lumbar interbody fusion procedures in the future.

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

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

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

There will be no cost to you for participating in this study. The costs for your standard of care procedures will be billed to you or your insurance.

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

You will receive a payment of $50 each time you complete the following visits: 3 months, 1 year, and when applicable, 2 years. You will receive a payment of $100 for completing the 6 month visit. You will receive payment after each completed visit.

By law, payments to subjects are considered taxable income.

11. 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 Wexner 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.

12. 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.

13. 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.

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;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Physical exams
  Laboratory, x-ray, and other test results; and

- Records about the study device

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- 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;
- 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 record.

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

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

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

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. 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 researchers. 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.

VIII. 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 and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. 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. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr. Andrew Grossbach at 614-293-8714**.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact:

HIPAA Privacy Officer
Suite E2140
600 Ackerman Road
Columbus, OH 43202
614-293-4477

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. Andrew Grossbach at 614-293-8714**.

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 combined consent and HIPAA research authorization 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)**
Relationship to the subject	**AM/PM** **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