Study Title: **A Prospective, Single Arm Study of Patients Undergoing Posterolateral Lumbar Fusion (without Interbody) Supplemented with ViviGen Cellular Bone Matrix**

Principal Investigator: **Andrew Grossbach, MD**

Sponsor: **DePuy Synthes**

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Document: Informed Consent Form and HIPAA 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?

This study is being done to collect data about a product called ViviGen. ViviGen is a type of bone graft that contains living bone cells; it is rich in bone proteins that provide elements to stimulate new bone growth, bridging your bones together to allow them to fuse.

You are being asked to participate in this study because you are scheduled to undergo a posterolateral lumbar fusion (PLF) using the Vivigen device as part of your standard medical care. This is not an experimental treatment and you would undergo the same surgery if you were not participating in this study. A PLF procedure is a surgery done to stabilize the spine and reduce pinching on the nerves coming off of the spinal cord to

relieve your leg pain. The study team would like to collect data from your medical records about your health before, during, and after the procedure in order to learn more about the patient outcomes following PLF surgery with the Vivigen device.

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

Approximately 50 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, the study team will access your medical records within 60 days prior to your surgery in order to collect information about your demographics (such as your birth year and gender), medical history, and current medications and therapies.

After you have your PLF surgery, which has been scheduled as part of your standard medical care, the study team will access your medical records to collect data from during your surgery as well as at your regularly scheduled follow-up visits. These follow-up visits will occur approximately 6 weeks, 3 months, 6 months, 12 months, and when applicable, 24 months after your surgery.

At your follow-up visit 12 months after your surgery, you will be asked to undergo a computed tomography (CT) scan. A CT scan is way to make x-ray images of the inside of the body. The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures that show structures inside your body more clearly than regular x-ray pictures. During the procedure, a technologist will take you into the CT scan room where you will lie down on the patient table (usually on your back) inside of the CT machine. It is very important not to move during certain parts of the test. This CT scan is the only procedure you will undergo only for this research. All other procedures would take place even if you were not participating in this study.

4. How long will I be in the study?

The study team will collect information from your medical records beginning 60 days prior to your surgery and continuing for up to 24 months after your surgery. The only procedure you will complete for this study alone is the CT scan 12 months after your surgery. The CT scan will take approximately 15 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?

Risk of Loss of Confidentiality

There is a potential risk of loss of confidentiality. However, every effort will be made to protect your privacy and confidentiality. No individual identification (such as names, initials, and dates or birth) will be used in any reports or publications resulting from this study.

Radiation Risks

If you take part in this research, you will have a CT scan done, which uses radiation. The radiation dose from this will be about 3 millisievert. To give you an idea about how much radiation you will get, we will make a comparison with an everyday situation. Everyone receives 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 10 extra months' 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 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 is very low. 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.

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

You will not receive any benefit from participating in this study. However, the information gained from this research will provide important information about PLF procedures using the Vivigen device, which may help other patents 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.

You can still undergo the PLF surgery without participating in this research.

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

There will be no cost to you for participating in this study. The cost of the 12-month follow-up CT scan will be covered by the research program.

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

You will receive a payment of $50.00 for completing each of your scheduled follow-up visits. If you complete all possible visits, you will receive up to a total of $250.00. You will receive payment at each 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).

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
- 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;
- Others: DePuy Synthes

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 43201
Phone: 614-292-4477

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