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

Study Title: Evaluation of the efficacy of radiofrequency-based debridement vs. mechanical debridement for the treatment of articular cartilage lesions.

Principal Investigator: Christopher Kaeding, MD

Sponsor: Smith & Nephew, Inc.

Dr. Flanigan, a researcher helping to perform this study, has a personal financial interest in Smith & Nephew, the company sponsoring this research. As a result, Dr. Flanigan could financially benefit from the testing and sale of the Werewolf Coblation System. The Ohio State University Institutional Review Board and the University's Conflict of Interest Advisory Committee have reviewed the financial interest and determined that it poses no additional significant risk to the safety of participants in the study or to the integrity of the research. Any questions about this financial relationship can be answered by Dr. Christopher Kaeding (614-293-8813), who has no personal financial interest in Smith & Nephew.

- **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 participate in this research study because you require an arthroscopic knee procedure for the treatment of a chondral lesion and torn meniscus. This study will

evaluate 2 different treatments, Mechanical Debridement (i.e., a mechanical shaver that removes areas of damaged tissue) and Radiofrequency Debridement (i.e., electrical energy that removes areas of damaged tissue), used to treat the chondral lesion in your knee. Your torn meniscus will be treated per standard of care by your study doctor.

All of the Mechanical Debridement and Radiofrequency Debridement devices being used in this study have obtained clearance by the U.S. Food and Drug Administration (FDA) for commercial use and are currently being used on the market.

The study doctor would normally use any one of the methods, Mechanical Debridement or Radiofrequency Debridement, to treat your knee, but right now it is not known if one of these methods is better than the other. This study is being conducted to see whether Radiofrequency Debridement is as effective as Mechanical Debridement in patients with knee problems such as yours.

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

A total of 82 will take part. You will be randomized at a 1:1 ratio into the Werewolf Coblation wand radiofrequency debridement treatment group (electrical energy used to precisely remove damaged tissue at relatively low temperatures) or mechanical debridement treatment group. This will be determined by a random process (like flipping a coin). For this study you will be randomized at a 1:1 ratio, which means that you have a 50% (1 in 2) chance of receiving the Werewolf Coblation wand radiofrequency debridement and 50% (1 in 2) chance of receiving mechanical debridement.

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

Today you will complete 4 questionnaires about your physical activity level as well as your knee symptoms. You will also have repeat x-rays and MRI if your most recent imaging is greater than 3 months old. Repeat x-rays are standard of care and will be billed to your insurance. The repeat MRI may or may not be considered standard of care. This will be determined by the physician. If your MRI is considered standard of care, it will be billed to your insurance. However, if the indication for the MRI is only due to the study requirements, the MRI cost will be covered by the study.

On the day of surgery, additional information regarding your procedure will be collected by a member of the research staff. Your treatment group will be randomly assigned during your surgery if you fulfill all criteria for the study. You will not be made aware of which treatment you have received until you have completed the research study.

<u>Photographs may be taken of your knee before, during, and after the surgery; however, your identity will not be revealed.</u>

You will complete additional surveys and receive a physical assessment by the surgeon at the following visits after your surgery: 10 days, 6 weeks, 6 months, and 12 months. At each follow-up visit, you will be asked general questions about your health. It is anticipated that the additional time to complete these activities will add 20-30 minutes to your visit. Office visits at 10 days and 6 weeks are considered standard of care and will be covered by the global period of normal post-operative care bundled into the global surgery fee billed to your insurance. Office visits at 6 months and 12 months are not considered standard of care, and will be covered by the study.

You will complete weekly online surveys from 1 week to 6 weeks post-op through an online data collection system called RedCap.

You will have x-rays and an MRI performed at your 12 month visit. An MRI is a magnetic resonance image that will show the interior area of your knee following surgery. It is anticipated that the MRI will take up to 1 hour to complete at this visit. X-rays performed at this visit are anticipated to add 15-20 minutes to your visit.

The results of this study and the collection of images (X-rays and/or MRI) may be used for future publications. If the results of the study are made public, information that identifies you will not be used.

4. How long will I be in the study?

You will be in the study from today up until one year after the date of surgery.

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?

The potential medical risks associated with the study device are prolonged surgery time due to device breakage or malfunction, subject burn, and/or inadvertent tissue removal.

The results of this surgery cannot be guaranteed. It is possible that the surgery will not reduce the pain or disability felt before surgery. In addition, the pain or disability may be worse after the surgery. It is possible that by being in the study, you can have problems and/or side effects not known at this time. There is some element of this risk in all surgeries, whether or not you receive the study device.

If you choose to take part in this study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the study, that might cause you to change your mind about continuing in the study. You may be asked to sign a new consent form if this occurs.

Participating in more than one study may increase risks to you and may affect study results. You should tell your study doctor if you are considering joining another study.

Loss of confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality as much as legally possible.

Women as Study Subjects

If you are a woman and are pregnant you cannot be in this study. If a woman is pregnant or nursing a child when she has medication associated with surgery there may be risks to the unborn baby or nursing child. If you are a woman who can become pregnant, you must have a pregnancy test prior to any surgery to check that you are not pregnant.

If you think that you are pregnant during the study, you must tell the study doctor immediately. If you become pregnant before the surgery, you will be removed from the study.

MRI

There are risks from an MRI if you are pregnant or have one of the following: an artificial heart valve, pacemaker, metal plate, pin, or other metallic objects in your body (including bullets or shrapnel). You may also become anxious or claustrophobic from lying in a tight space without moving. The MRI scan does not cause any pain and does not expose you to x-ray radiation. The effects of the magnetic fields in a MRI scanner have been widely studied, and there are no known risks from being exposed to the magnetic fields

Radiation Exposure from X-ray

X-rays are considered to be low risk. X-rays expose you to radiation. Most radiation procedures use very small amounts of radiation that are not expected to cause harm. However, the exposure risk is cumulative over a lifetime, and the total should be kept as low as possible.

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

You may not benefit directly from participating in this study. If you choose to participate in the study, your condition may or may not improve. The potential benefits of the study device are minimal thermal penetration and precise and efficient tissue removal. The information collected in this study to determine the effectiveness of Radiofrequency Debridement may benefit future patients undergoing arthroscopic knee surgery.

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?

All costs that are part of your usual medical care, such as your surgery and physical therapy, will be charged to your insurance company if you have such coverage. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this study. If you have no health insurance you will be held responsible for paying all costs of the study.

Costs which are not associated with standard treatment, such as costs of MRI required specifically for this research study, will be paid for by the sponsor.

While you are in the study, you may still need to get regular medical care. You will still have to pay for the costs of your regular medical care that are not a part of this study. To find out more about costs, you can ask the study doctor or study personnel.

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 these costs because you are taking part in a research study.

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

You will receive the following payment(s) for your participation:
You will be compensated $50.00 for the pre-op, 10day, 6 week, and 12 month visits. You will be compensated $20.00 total for all your online questionnaires (1wk-6wks) and $20.00 for the 6 month visit. Payments for participation are to cover meals and transportation for a maximum of $240. You will receive check payments by mail within 30 business days once you have completed each study 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.

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify

you. Your data will be protected with a code to reduce the risk that other people can view the responses.

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:

HIV / AIDS
Hepatitis infection
Sexually transmitted diseases
Other reportable infectious diseases
Physical exams
Laboratory, x-ray, and other test results
Diaries and questionnaires
The diagnosis and treatment of a mental health condition

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

Responsible Research Practices, and Western Institutional Review Board® (WIRB®)

IV. Your information may 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.

If the results of this study are made public, information that identifies you will not be used.

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**:**

Christopher Kaeding, MD at (614) 293-8813 (24 hours)

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, 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**:**

Christopher Kaeding, MD at (614) 293-8813 (24 hours)

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