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

Study Title:	**SPASM: Randomized, Sham Controlled Trial of Dorsal Root Rhizotomy Stereotactic Radiosurgery versus Standard of Care for Spasticity Associated with Stroke, Spinal Cord Injury & Cerebral Palsy**
Principal Investigator:	**Evan M. Thomas, MD, PhD**
Sponsor:	**Varian Medical Systems**

- **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.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This study is being done to determine the safety and effectiveness of high dose focused radiation to a part of your spine called the spinal dorsal root using a technique called stereotactic radiosurgery (SRS) in patients with spasticity. If you agree to participate in the study, you will be randomly assigned to either receive radiosurgery or not to receive radiosurgery. As part of your participation in the study, you will be asked to complete follow-up visits at 2, 6, 12, and 24 months. If you are randomized to the group without radiosurgery,

you will be allowed to crossover to the group receiving radiosurgery after your 6 month visit if you desire.

1. Why is this study being done?

This study will evaluate the safety and effectiveness of high-dose focused radiation to the spinal dorsal root using a technique called stereotactic radiosurgery (SRS) in patients with spasticity. Stereotactic radiosurgery is the precise high dose application of radiation to a small area. A dorsal root rhizotomy is the intentional damage or change to the root of the nerve coming out of the spinal cord that carries sensory information. In patients with spasticity, this is the part of the nerve that sends too much signal to the spinal cord and causes heightened reflexive spasticity. Radio surgical rhizotomy is noninvasive and uses focused radiation to attempt to change the function of the nerve without destroying it. The purpose of this study is to see if using 1 treatment session of SRS for spasticity is safe and helps your spasticity.

You are being asked to take part in this study because you have spasticity that is still present despite medical or other interventional management.

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

It is anticipated that up to 25 patients will take part in this study at Ohio State.

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

Before you begin the study:

The following will take place to find out if you can be in the study. These exams, tests, or procedures are sometimes part of regular medical care. If you have recently had them done, they may not need to be repeated. Your medical record will be reviewed by the study doctor to determine which tests and procedures will be needed.

- A physical examination
- Your medical history will be collected, and you will complete an interview that includes questions about your past and current health.
- Evaluation of your spasticity and its effects on your quality of life. You will be assessed and asked questions. Your spasticity and its effect on your quality of life will be assessed.
- Evaluation of your ability to carry out daily activities. You will be asked questions about what type of daily activities you can do.
- Imaging of your spine with Magnetic Resonance Imaging (MRI) and Computer Tomography (CT) imaging.

- MRI scans create images of the body using a strong magnet and radio waves. You will be asked to remove all metal objects from your person before entering the scanning room and may be asked to remove clothing and put on a hospital gown or scrubs. During the MRI scan, you will lie on a table and be confined toa small space inside a cylindrical machine (tube). The MRI will take about 1 hour. Although you will be asked not to move or talk during the MRI procedure, you will be able to communicate with the MRI Technologist by pressing a call button that will be within your reach. The Technologist will observe you during the entire time that you are in the MRI scanner.
- CT is a 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 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 inside of the CT machine. During the study, you will be asked to hold your breath so that the pictures will not be blurred. The machine will make some noise, and the table will move during the scan. The scan will take about 1 hour.

- Electromyogram (EMG) and nerve conduction velocity (NCV) testing to see how your muscles and nerves are working. This will only be done if it is part of your standard of care treatment. If you are not undergoing EMG and NCV as part of your regular medical treatment, it will not be done separately for this study.
  - EMG is a procedure that assesses the health of your muscle and nerve cells by measuring the electrical activity of your muscles as they move. An EMG measures these impulses through a needle, which acts as an electrode, injected into the muscle tissue. The EMG will take approximately 30-90 minutes.
  - A NCV test measures how fast electrical impulses move through your nerves. During the test, your nerve will be stimulated, and the nerve activity recorded with electrode patches attached to your skin. The NCV will take approximately 30-90 minutes.

During study treatment:

- You will undergo another CT scan. This CT scan is used to design a radiosurgery treatment plan. It will take approximately 1 hour.
- You will be randomly assigned (like flipping a coin) to either the treatment group or the “sham” group. There is a 50/50 chance of being in either group. You will not be able to choose what group you are assigned to, and you will not know what group you are assigned to.
  - Regardless of which group you are assigned to; you will be asked to lie on the treatment table and a device will rotate around you. This will take approximately 30-90 minutes.

- **If you are assigned to the treatment group,** you will receive a radiosurgery treatment to one or more of your affected nerve roots. The device rotating around you will emit invisible, high-energy x-rays.
- **If you are assigned to the "sham" group,** you will not receive treatment. The device rotating around you will not emit x-rays.

After you are finished with treatment:

You will be asked to complete follow-up visits at 2 months, 6 months, 12 months, and 24 months after treatment. Each follow-up visit will take 45 – 90 minutes and include the following:

- Physical examination
- Evaluation of your spasticity and its effects on your quality of life
- Evaluation of your ability to carry out daily activities
- Imaging of your spine with MRI and CT imaging
- EMG and NCV testing (only at the 6 month visit). This will only be done if it is part of your standard of care treatment. If you are not undergoing EMG and NCV as part of your regular medical treatment, it will not be done separately for this study.

In addition, the researchers will access your medical records to obtain information related to your demographics, medical history, and spasticity. If you have had photos taken as part of your standard of care spasticity assessment, these may be obtained from your medical records as well.

If you are randomized to the group without radiosurgery, you will be allowed to crossover to the group receiving radiosurgery after your 6 month visit if you desire.

4. How long will I be in the study?

You will be in the study for 24 months after treatment.

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?

Risks related to the SRS Treatment:

Likely:

- Dullness or changing of sensation in the area being treated for spasticity

- Changes in muscle spasm patterns in the area being treated for spasticity

Less Likely:

- Reddening of the skin in the area treated with radiation
- Pain at the site of radiation treatment
- Swelling around the area of the treatment
- Scar tissue formation in the area of treatment
- Changes in how your limb being treated feels

Rare but potentially serious:

- Injury to the spinal cord near the area receiving treatment
- Necrosis or injury to skin or soft tissue near the treatment area

Information for Women of Childbearing Potential

If you are pregnant, you cannot take part in this study. You should not become pregnant if you decide to take part because the radiation can affect an unborn baby. This study may be harmful to a nursing infant or an unborn child. If you are unwilling to use adequate birth control measures to prevent pregnancy, you cannot participate in this study. Reliable methods of birth control are considered to be: abstinence (not having sex), intrauterine device (IUD), tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts). An acceptable, although less reliable method involves the careful use of condoms and a spermicidal foam or gel and/or a cervical cap or sponge. It is important you understand that you need to use birth control while on this study and for 6 months after treatment ends. If you suspect that you are pregnant or if you become pregnant while you are on this study, you must tell your doctor immediately.

Radiation Risks

This research study involves exposure to radiation from CT scans of your spine and from the radiosurgical procedure. This radiation exposure is for research purposes only. The total amount of radiation that you will receive in this study is about 535.4 mSv and is approximately equivalent to a whole body exposure of 89 years of exposure to natural background radiation. Most of this radiation is concentrated within the nerve root being treated. The exposure to the body as a whole is much less.

Loss of Confidentiality

There is a risk of loss of confidentiality, but many precautions will be taken to protect your information.

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

You may or may not benefit from taking part in this study. SRS for spasticity may be effective in treating spasticity. However, there is no proof of this yet.

The information gained from this study will help doctors learn more about SRS as a treatment for spasticity, which could help other patients in the future.

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

Your other choices include getting the current standard of care treatment for spasticity without being in a study or taking part in another, unrelated study that may be available.

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?

The costs of your standard medical care will be billed to you and/or to your insurance company in the usual manner.

You and your health insurance plan are responsible for all routine costs associated with this study. Routine costs are costs that are covered by Medicare in connection with studies such as this one, even if Medicare is not your insurance provider.

All routine costs will be billed to your health insurance plan, but there is no guarantee that your health insurance plan will cover all routine costs. Even where such insurance coverage is provided, you may still have to pay some costs such as copayments, coinsurance, or deductibles for the covered items or services. You should contact your health plan to discuss its coverage policy for items or services provided during a research study.

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

You will not receive payment for participating in this study.

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 research participants.

13. Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

14. 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).

If we find information that significantly impacts your health, we will share it with you. This includes information as to the efficacy of the treatment or potential adverse effects of treatment.

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.

15. 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
  - Diaries and questionnaires
- 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.

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact **Evan Thomas, MD at 614-293-8415.**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the HIPPA Privacy officer located at **650 Ackerman Rd Columbus, OH 43210, 614-293-4477 or 614-293-7672.**

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 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 **Evan Thomas, MD at 614-293-8415.**

Dr. Evan Thomas, a researcher helping to perform this study, is a paid consultant for Varian Medical Systems, Inc., the manufacturer of the devices being tested. A conflict of interest committee at Ohio State has reviewed this information and determined that Dr. Thomas's involvement presents no additional significant risk to the study's participants. Any questions about this information can be answered by Dr. Joshua Palmer, (614) 293-8415

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

Optional photo consent: Please check one of the boxes below to indicate whether you allow the research team to collect any available photos related to your spasticity from your medical record for the research.

☐ I **agree** to have photos collected from my medical records for this research.

☐ I **DO NOT agree** to have photos collected from my medical records for this research.

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

435