Framing Eighteen Coils in Cerebral Aneurysms Trial (FEAT)

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Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Dr. Michael Froehler
Study Title: Framing Eighteen coils in cerebral Aneurysms Trial (FEAT)
Institution/Hospital: Vanderbilt University Medical Center

Revision Date: 4/23/2015

This informed consent applies to: Adults

Name of participant:_____Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have been diagnosed with an intracranial aneurysm (a bubble in the wall of a vessel in your brain). You and your treating doctor have also decided that your aneurysm will be treated using endovascular coils (an alternative treatment to surgery where platinum coils will be placed in your aneurysm using X-ray guidance).

Your physician has also already determined that you could receive one of two FDA (United States Food and Drug Administration) approved (not research) framing coils (the first coil placed inside of an aneurysm in order to "frame" it and provide an initial structure for support). This study hopes to determine if the use of one FDA approved framing coil when compared to another FDA approved framing coil will show better results.

Both of these coils are used routinely at the facility you are being treated at. There is currently no evidence to show if one is better or worse than the other. If you choose not to participate in this research trial, your aneurysm could still be treated using either of these framing coils.

2. What will happen and how long will you be in the study?

In routine clinical practice (not research) there are many different types of endovascular coils that are used to treat aneurysms. Many physicians will routinely use multiple different types of coils inside of one aneurysm. Many physicians also routinely work with a wide variety of FDA approved coils in their regular practice.

If you decide to participate in this research study, you will be randomly assigned to one of two FDA approved framing coils. You will be assigned by a computer to receive either Eighteen platinum framing coils (0.014-0.0155 inch) or standard platinum framing coils (<0.014 inch). You will have a 50:50 chance (much like your chances of getting heads verses tails when flipping a coin) of receiving one coil or the other.

If at any time during the procedure your physician feels that your aneurysm could be more safely or effectively treated with another type of coil, your physician will make the choice to place whatever coil they feel is best for you (regardless of what the computer assigned you to).

You will also be strictly monitored for any events that could be considered to be related to your participation in this research trial. If any adverse or negative events occur from your participation in this research trial, we will ask you to provide specific information on the events and will report them appropriately (per the research protocol).

You will be in this study for 18 months, if you choose to continue until the end. You will receive standard follow-up care between 3-6 months and between 12-18 months.

Please review the following schedule of events that will take place while you are in this study. The items that are identified with "Research" are the only items that are being performed for research purposes only. All other items will occur as part of your routine care.

Visit Schedule

	Screening and Enrollment	Embolization Procedure	Discharge	3-6 Month Follow-Up	12-18 Month Follow-Up	Unscheduled Visit(s)
Informed Consent (Research)	X					
Inclusion/Exclusion (Research)	X					
Randomization (Research)	X					
Chart Review (Research)	X					
Hunt Hess	X					
Fisher (if applicable)	X					
WFNS (if applicable)	X					
Modified Rankin (Research)	X		X	X	X	X
NIHSS (Research)			X	X	X	X
Research Data Collection (Research)	X	X	X	X	X	X
Clinical Evaluation (Research)	X		X	X	X	X
Imaging		X		X	X	X (if indicated)
Embolization		X				
Re-Treat (if applicable)				X	X	X
Evaluate for AEs/SAEs (Research)	X	X	X	X	X	X

Informed Consent/Review of Inclusion and Exclusion Criteria/Chart Review

You are currently being questioned about giving your informed consent for this research study. After signing the consent, you may stop participating in this study at any time. We are also available to answer any and all questions that you may have about this study during your entire time participating in the study. We will review your medical chart and the studies previously determined Inclusion and Exclusion criteria before we determine that you are eligible to

participate in this study. We may need to ask you questions in order to determine whether or not you are eligible to participate.

Imaging

Standard of care follow-up imaging (which normally includes an angiogram) will be performed at 3-6 months and again at 12-18 months post-coiling. Pictures of your follow-up imaging will be de-identified (stripped of any information that could be linked back to you) and sent to an independent monitor for review.

Clinical Assessments

Your clinical status during study screening, your procedure, at 3-6-months, and at 12-18 months will be recorded for research purposes. This will include several standard neurological and physical exams (which should not take more than 30 minutes to complete).

Research Assessments/Clinical Assessments/Neurological Exams

Research assessments could take between 5 and 30 minutes to complete (depending on your condition). These assessments are evaluations of whether you have had anything negative happen to you during your participation in the study that could be related to the device you received during your procedure. If it is felt that something happened to you because you participated in this study, we will need to collect additional information on that negative event or outcome.

3. Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

You and your treating physician have already determined that your aneurysm will be treated endovascularly (an alternative treatment to surgery where platinum coils will be placed in your aneurysm using X-ray guidance). The risks of the procedure itself should be explained to you by your physician as part of your routine clinical care. The risks of the procedure itself will not increase or decrease due to your participation in this study. Below are some of the known clinical risks of undergoing endovascular aneurysm coiling:

1. Bleeding
2. Infection
3. Allergic reaction to contrast or medication
4. Hydrocephalus/inflammation
5. Blood vessel injury or thrombosis
6. Kidney damage or failure
7. Stroke
8. Vessel dissection/rupture
9. Aneurysm perforation
10. Clot formation
11. Device malfunction
12. Disruption of clot from aneurysm
13. Distal emboli resulting in stroke
14. Death
15. Paralysis
16. Cardiac arrest
17. Brain damage

You do need to consider that a computer will be deciding which of the two FDA approved framing coils will be used to treat your aneurysm. Again, your physician would not have approached you about participating in this study if they did not feel that you would equally benefit from either of the framing coils being used in this study. If at any time, your treating physician believes that another type of coil would be more beneficial in treating your aneurysm, your physician will use that coil regardless of which coil type was chosen for this study.

The study team will be collecting additional information from you for research purposes. They will also be accessing and storing copies of your medical records for research purposes. Copies of your medical record might include, but will not be limited to, your history, contact information, physical exams, procedure notes, medications, neurological exams, diagnostic images, etc. These records will be kept digitally in secure files and on paper files behind a locked office door. Only approved research personnel will have access to this information. Although the research team will work very hard to keep this personal information from reaching anyone that is not authorized to view it, there is still no guarantee that your information can be kept completely confidential.

5. Risks that are not known:

There are no known risks of receiving one framing coil verses the other framing coil at this time. Both framing coils are FDA approved and used routinely throughout the country as standard of care. If we become aware of any new risks throughout the course of this study, you will be notified immediately.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt, Stryker, and the investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt University Medical Center to treat the injury.

There are no plans for Vanderbilt or Stryker to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study include the finding of scientific evidence that one routinely used framing coil over the other routinely used framing coil will lead to a better long-term result.
b) You will not directly benefit from participating in this study.

8. Other treatments you could get if you decide not to be in this study:

If you decide not to participate in this study you can still receive either of these framing coils inside of your aneurysm.

9. Payments for your time spent taking part in this study or expenses:

You will not be paid to participate in this research study.

10. Reasons why the study doctor may take you out of this study:

At any time, your doctor can choose to take you out of this study. If you are taken out of this study, you will be given the reason. Some reasons for withdrawing you from this study might include your inability to return for follow-up, your neurologic outcome drastically deteriorating (as defined in the research protocol) before your aneurysm is repaired, your treating physician feels that you would not equally benefit from both coils being used in this research study, etc.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Michael Froehler at (615) 936.0060.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry.

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.

14. Confidentiality:

Your electronic research data will be stored in a secure, web-based program.

All of your paper research data will be kept in The Department of Neurosurgery in the Clinical Research Office. However, copies of your medical record (such as your interventional procedure note, interventional follow-up notes, a radiologist's dictation on your imaging exams, your history and physical, and documents containing information related to any adverse events that you may have experienced) will be kept in paper research charts and stored electronically for source documentation. This paper and electronic data may contain protected health information in order to verify the source for all or your collected research data. The actual paper data will be kept in clinical research charts behind a locked office door.

There are no study specific issues that might increase the risk of breach of your confidentiality. You will be assigned a unique study ID in order to decrease the risk of a breach in your confidentiality. Your unique study ID number will be used to identify your information that is stored outside of the paper research chart and outside of the secure electronic data system. All of your protected health information that was collected at Vanderbilt University Medical Center will remain at Vanderbilt University Medical Center in paper research charts kept behind a locked office door in The Department of Neurosurgery and a copy of that data will be entered into the secure database.

Stryker and/or Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Stryker, Vanderbilt, Dr. Michael Froehler and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Research data will be kept until 7 years after study completion. At that time, all research records will be shredded and destroyed.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Michael Froehler and his study team may share the results of your study and/or non-study linked information (including but not limited to your history, contact information, physical exams, procedure notes, medications, neurological exams, diagnostic images, etc.) as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, FDA, National Institutes of Health, Representatives of Stryker, or insurance companies for billing purposes. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least seven years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Michael Froehler in writing and let him know that you withdraw your consent. His mailing address is:

Department of Neurological Surgery
Vanderbilt University Medical Center
4340 Village at Vanderbilt
Nashville, TN 37232

At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

I, _____ [name of decision-maker/surrogate], am the _____ [state relationship to participant] of_____[state participant's name]. I have read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____ [participant's name]. I believe receiving such treatment would be in the interests of_____[participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____ ___/___/____
Signature of Health Care Decision-Maker/Surrogate Date

_____ ___/___/____
Signature of Witness Date

_____ ___/___/____
Name and Signature of person obtaining consent Date

VANDERBILT UNIVERSITY MEDICAL CENTER
Department of Neurosurgery

Dr. Michael Froehler Clinical Research Office

version 9.21.12

Consent Documentation

Date of Consent:_____ **Study/HDE Title:**_____ **Patient Initials:** _____

By signing below, I hereby certify that each of the following was completed as part of the Informed Consent Process:

1. The study and Informed Consent Document (ICD) were explained and reviewed with the subject/surrogate.
2. The subject/surrogate was provided adequate time to review the ICD and to discuss study participation with family/others.
3. The subject/surrogate was provided the opportunity to ask questions about the study and to have those questions answered satisfactorily.
4. The subject/surrogate demonstrated understanding of the study by verbalizing appropriate responses about the study's purpose, risks, and benefits.
5. The subject/surrogate agreed to take part in the study and signed the ICD prior to the study interventions (or participation in the study).
6. The Consent Process was witnessed by a third party.
7. A copy of the signed and dated ICD was given to the subject/surrogate.

Complete this section only if a surrogate was used:

1. Why was a surrogate used?
   - ☐ Subject was disoriented
   - ☐ Subject was comatose
   - ☐ Subject was intubated/sedated
   - ☐ Other; explain:
2. Who made the determination to use a surrogate? _____
3. Indicate the relationship of the surrogate to the patient:
   - ☐ Judicially appointed representative
   - ☐ Spouse
   - ☐ Adult child
   - ☐ Parent/Legal Guardian
   - ☐ Adult sibling
   - ☐ Other adult relative
   - ☐ Close friend of subject

**If a surrogate higher on the hierarchy did not serve as the surrogate, indicate why:*

- ☐ Non-existent
- ☐ Unreachable
- ☐ Other; explain:

Notes:

Date of IRB Approval: 10/20/2020
Date of Expiration: 10/19/2021

Institutional Review Board

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