Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Manus Donahue **Revision Date: 4/02/12**
Study Title: Characterizing Hemodynamic Compensation and Stroke Risk in Stenosis Patients
Institution/Hospital: Vanderbilt University

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 we are investigating the brain perfusion in patients with intracranial stenosis.

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

Following the routine brain MR acquisition which your doctor has ordered for you today, we would like to perform one additional sequence, while you are in the MRI scanner. That sequence is a research sequence. The additional sequence will use a special technique to identify how your brain is perfused. It will take approximately one additional minute of scan time.

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

There is no cost to you for taking part in this study.

For this study it includes the research only procedures noted in section 2 above.

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:

The only known risk you can expect for participating in this study is a rare (<1%) risk that protected health information from you would be disclosed, as part of data processing or data analysis. We will not need to start an IV or give you contrast for the research sequence. The additional sequence will not expose you to radiation.

5. Risks that are not known:

Because this imaging sequence is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

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

If it is determined by Vanderbilt 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** to treat the injury.

There are no plans for Vanderbilt 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:

We believe this imaging sequence will provide us with better information regarding brain perfusion in patients with intracranial stenosis, which could help us better understand and treat this disease.

The benefits you might get from being in this study. We will be evaluating how your brain is perfused, including how your brain has compensated for vessels that have stenosed.

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

This information has traditionally been obtained from cerebral angiography, which is invasive and has a much higher complication rate than the MRI you will have today

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

None

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

If you are not comfortable in the MRI scanner, the study would be discontinued based on your request.

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.

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. Manus Donahue at (615) 322-8350.

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. Confidentiality:

The MRI scans from study patients will be reviewed by Drs. Strother, Ayad, and Donahue. The findings will then be entered onto the electronic ASL Data Collection Sheet. This electronic database will only be accessed and saved on Vanderbilt computers in the offices of Drs. Ayad, Strother, and Donahue. Images from cases showing examples of findings that correlate with changes in cerebral vascular reserve will be de-identified before inclusion in any potential publication or presentation of the results of this pilot study. At the conclusion of the study, the de-identified data will be retained indefinitely by Dr. Strother. The data with protected health information will be destroyed at the conclusion of the study. Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr Strother and her 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.

14. 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. Donahue and his study team may share the results of your study and/or non-study linked MRI scans, 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 and the Vanderbilt University Institutional Review Board. 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 six 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. Any research data that has been put into 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. Strother in writing and let her know that you withdraw your consent. Her mailing address is 1161 21st Avenue South, Nashville, TN 37232-2675. 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.

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