**LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER in NEW ORLEANS**
**Informed Consent Form**

**1. Study Title:** Q-CAMP: Non-Invasive Computer-Aided Phenotyping of Vasculopathy (Seeing Beyond the Image in Vascular Disease)
**Sponsor:** Elucid Bioimaging, 225 Main St, Wenham, MA 01984

**2. Performance Sites:**

- University Medical Center New Orleans – 2000 Canal St, New Orleans, LA 70112
- West Jefferson Medical Center – 1101 Medical Center Blvd, Marrero, LA 70072
- University Medical Center Ambulatory Care Building – 2000 Canal St, New Orleans, LA 70112

**3. Investigators:**
Principal Investigator: Malachi Sheahan III, MD, 4500 10th Street, Suite C, Marrero, LA 70072, Office 504-412-1960, 24-hour number 504-412-1960

Co-Investigators: 1542 Tulane Ave, Suite 734B, 504-568-4748 or 504-412-1960
1. Larry Hollier, MD
3. Tapash Palit, MD
4. Bruce Torrance, MD
5. Leonard Bok, MD
6. William Risher, MD
7. William Newman, MD
8. Raman Danrad, MD

For any reseach related injury, please contact: **Malachi Sheahan MD at 504-412-1960**

**4. Purpose of Study:** This research study is to see if the results based on images obtained from your magnetic resonance imaging (MRI is a medical imaging technique to look at anatomy) of the atherosclerotic plaque in your artery match what is seen when we take the plaque out of your artery. You are a candidate for this research study because your artery contains atherosclerotic plaque and you require surgery to remove it. We wish to undertake this study because we want to know how well MRI can pick up the different properties of the plaque. Atherosclerosis (the plaque in your artery) is caused by the long term injury of arteries that results in inflammation and plaque formation within the artery. Current ways, such as ultrasound and angiography, to view the plaque pick up some characteristics like size and shape, but do not pick up others which may be important for predicting things like stroke. MRI is an imaging test in which is done by using magnetic fields. Harmful radiation is not used. This study will see how MRI tells the difference in various plaque structural and functional components. We will use your pre-surgical MRI imaging, and compare it to the post-surgical plaque specimen. The MRI data will be studied using a software program called vascuCAP™.

The imaging software used in this study is currently being studied, and has not been approved by the FDA or any other organization for use in patients outside of research trials. If you are eligible and choose to enroll in this research study, the anticipated duration of your study involvement will be approximately 1-2 months. We wish to enroll 110 local patients in this study.

**5. Description of the Study:** Below is the timeline which we will follow for this study.

| Q-CAMP Schedule of Events | | | |
|---|---|---|---|
| **Screening visit** | **Enrollment Visit** | **Imaging Visit** | **Day of Surgery Visit** |
| (Day -28 to -1) | Day 0 | (Day 0 - 30) | (Day of Imaging plus 0 - 30 days) |
| Medical/dental history review | Demographic information review | Urine pregnancy test for women of child bearing potential | Endarterectomy (is the general term for surgical removal of plaque from an artery)per standard site procedures |
| Blood pregnancy test for women of child bearing potential | Medical history review | MRI safety checklist review | Pathology sample collection |
| Medical and dental exam | Medication history review | Gadolinium (the contrast media used) contrast MRI | |
| | Alcohol and tobacco use history review | | |
| | Clinical exam | | |
| | Ultrasound of blood vessels | | |

The following events will take place during the study:

- Histories: Medical, dental, medication, alcohol, tobacco, and demographic histories will be taken as outlined in the schedule of events table. The data may be collected by asking you questions or by reviewing your medical record.
- Clinical exams: Clinical exams will be performed during the screening and enrollment visits and throughout the study as appropriate. These are standard exams to determine your general and vascular health.
- Pregnancy testing: If you are a women of child bearing potential you will undergo the following pregnancy tests:
    - Blood pregnancy testing from a single blood collection during screening
    - Urine pregnancy testing from urine sampling at the enrollment and imaging visits.
- Imaging:
    - You will receive an ultrasound of the affected blood vessels during the study. This will occur during time of enrollment. Ultrasound is a technique which uses sound waves to create images of your blood vessels and other tissue and is thought to be very safe.
    - You will also undergo an MRI with contrast media at the imaging visit. You will receive IV contrast which increases the ability of MRI to view your blood vessels. After the receipt of this contrast material you will lie still in the MRI machine. The total duration of MRI may be up to 90 minutes.
- Surgery: You will undergo a surgical procedure called an endarterectomy during which the atherosclerotic plaque will be removed from your artery. The procedure will be

described in a separate, non-study related consent form. The atherosclerotic plaque removed during the procedure will be sent to the pathology lab to be analyzed.

A description of this clinical trial will be available on http://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. The National Clinical Trials number for this study is **NCT02143102.**

**6. Benefits to Subjects:** A direct benefit to you personally will likely not occur by your participation in this study. The benefits seen by your participation in this study will be seen in future patients who get to benefit from this new technology.

**7. Risks to Subject:** There will be no additional risk to you by participating in this study. No additional procedures or imaging will be required of you by participating in this study. The only difference from the current way we would treat your disease is the new MRI software technology we will be using. Because of this, your risk by participating in this study is minimal. Your confidentiality will be assured due to your participation in this study.

Although no additional MRI other than what we would do normally is done, 2013 American College of Radiology (ACR) Manual on Contrast Media (a substance we inject during the MRI) stated the frequency of all acute adverse (bad) events after an injection of MRI contrast media is uncommon. Bad events can happen anywhere from 0.07-2.4% of the time. The vast majority of these events are mild. They include things like:

- coldness where we injection the contrast media
- nausea with or without vomiting
- headache
- warmth or pain at the injection site
- tingling
- dizziness
- itching
- allergic reaction
- rash
- hives
- shortness of breath.

Severe, life-threatening events are exceedingly rare. During the MRI process, we monitor you for these events. An important severe reaction to mention is something called nephrogenic systemic fibrosis (NSF). NSF is a condition whose onset is associated with contrast media injection. NSF is a severe disease that can scar your kidneys and not allow them to function normally. This can lead to hospitalization, kidney failure, and dialysis. NSF usually happens in patients with already low kidney function. We test you for low kidney function before giving you contrast media. Even so, NSF is extremely rare.

An injection outside your vein can occur. This is caused by a blown vein. The risk of this happening is estimated to be 1/2000 injections. An injection outside your vein may cause some combination of pain, redness, and swelling. This usually resolves on its own and does not require treatment. Severe skin ulceration can occur as well, but is rare.

Standard risk associated with the appropriate surgical procedure will be discussed with you prior to operation at the time of operation consent. Minimal to no risk will be accrued by you when the pathologist looks at your surgical specimen. The risk of death and/or major injury related to study participation is low and mainly is associated with the surgical procedure.

There is one blood draw during this study for women of child bearing potential. Risks include pain, bleeding, and infection of the blood collection site. Risk of a major complication is low.

**8. Alternatives to Participation in the Study:** The alternative is not to participate in this study. The alternatives if appropriate would include not doing the MRI, and doing a different imaging procedure. Proceeding to surgery with images that are appropriate to treat your disease will not be affected by you choosing not to participate in this study.

**9. Subject Removal:** The researcher may stop you from taking part in this study if at any time it is believed to be in your best interest; if you do not follow the study procedures; if the study is stopped. You could be taken off the study if your health worsens; if another treatment option appears to be appropriate; or for any other cause which prevents your continuing in the study.

**10. Subject's Right to Refuse to Participate or Withdraw:** Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may refuse to participate or withdraw from the study at any time without jeopardizing, in any way, your medical treatment at this institution in the present or future. Information already collected about you and sent to the sponsor will still be used. Tell the researcher if you are thinking about withdrawing from the study so that you may do so safely. If you decide not to continue participation in the study you should seek medical advice for alternatives. Should significant new findings take place during the course of the research that may relate to your willingness to continue participation, that information will be provided to you.

**11. Subject's Right to Privacy:** The results of the study may be released to the funding agency. Euclid Bioimaging Inc. If the results of the study are published the privacy of subjects will be protected and they will not be identified in any way. Your personal information may be disclosed if required by law.

**12. Release of Information:** Organizations that may inspect and/or copy your study-related medical records for quality assurance and data analysis include: the sponsor Euclid Bioimaging Inc., the LSUHSC-NO Institutional Review Board, and the doctors listed on page 1 of this consent form and their staff. While every effort will be made to maintain your privacy, absolute confidentiality cannot be guaranteed. Records will be kept private to the extent allowed by law.

**13. Financial Information:** The costs of all drugs, visits, procedures, study-related imaging, and unforeseen complications, to the extent not covered by insurance, will be covered by the sponsor. Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar conditions. The principal investigator will arrange for medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. This will be provided on a fee-for-service basis. There are no funds available to pay for any disability that results or for damages such as lost wages, etc.

You will be paid for your participation as reimbursement for your time and travel. Participating patients will receive $35.00 for each visit. You will not be paid for the initial screening visit. The total amount of $105 is provided for participation in the entire study.

**14. Signatures:** The study has been discussed with me and all my questions have been answered. Additional questions regarding the study should be directed to the investigators listed on page 1 of this consent form. If I have questions about subject's rights, or want to discuss problems, concerns or questions, or obtain information or offer input, I can contact the Chancellor of the LSU Health Sciences Center New Orleans at (504) 568-4801. I agree with the terms above, acknowledge I have been given a copy of the consent form, and agree to participate in this study. I have not waived any of my legal rights by signing this consent form.

_____ _____

Signature of Subject Date

_____

Printed Name of Subject

_____ _____

Consent Administered by Date

_____

Printed Name

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part.

_____ _____

Signature of Reader Date

_____

Printed Name

_____ _____

Signature of Witness Date

_____

Printed Name

The study subject is unable to sign and I certify that I am his/her legally authorized representative.

| Legally Authorized Representative | Signature | Date |
|---|---|---|

Reason for not obtaining patient consent:

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