Wake Forest®
School of Medicine

Department of Neurology/ Department of Internal Medicine
Section on Hematology and Oncology

THE FEASIBILITY AND BIOLOGIC EFFECT OF A MODIFIED ATKINS-BASED INTERMITTENT FASTING DIET IN PATIENTS WITH HIGH-GRADE ASTROCYTOMA (GLAD)

Informed Consent Form to Participate in Research
Roy Strowd, MD, Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have been diagnosed with an Astrocytoma, which is a type of brain tumor. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to learn more about the diet therapies in treating people with brain tumors. Specifically, the purpose of this research is to determine whether a new diet that is low in sugar and calories called the GLAD diet (GLioma Atkins-based Diet) is safe and feasible in people with brain tumors.

The GLAD diet used in this study is similar to a diet that is currently being used in the treatment of patients with severe seizures called the Modified Atkins Diet. This diet limits the number of carbohydrates that can be eaten each day. Recent evidence suggests that short periods of fasting is combined with this low carbohydrate Modified Atkins Diet, it may be helpful in the management of brain tumors. The current study is designed to test whether such a diet is safe and feasible in people with brain tumors.

Adults aged 18 years and older who have been diagnosed with a brain tumor, who have completed the initial radiation and combined chemotherapy, who are greater than 3 months from the completion of radiation, and who do not have any active illnesses or history of an illness that would prevent safe initiation of this diet may participate in this research study. Both men and women may participate.

How Many People Will Take Part in the Study?

25 people at 2 research sites will take part in this study, including approximately 12 people at Wake Forest Baptist Medical Center.

What Is Involved in the Study?

The study team will review your medical history, cancer treatment history, medications, as well as laboratory, pathology reports and MRI scans that were performed as part of your regular care. This is done to confirm that you are eligible to participate in the study.

If you agree to participate in the study you will have the following study visits:

- Baseline/Screening visit with the study doctor and study dietitian
- Week 2 visit with the dietitian
- Week 4 visit with the study doctor and study dietitian
- Week 6 visit with the study dietitian
- Week 8 (End of Study Visit) with the study doctor and study dietitian
- Follow Up questionnaire will be done 6 months after the Week 8 End of Study Visit, either by phone or e-mail.

Baseline/Screening

You will come to the Clinical Research Unit at Wake Forest Baptist Medical Center for a screening visit. During the Baseline/Screening visit:

- You will meet with one of our study dietitians and review the low carbohydrate GLAD diet. This diet will be explained in detail by the study dietitian and you will be provided with written information and a video that explains the diet.
- Prior to beginning the diet, you will need to have 2 tablespoons of blood drawn for us to check your blood counts, kidney function, liver function, and electrolyte levels prior to starting the diet. All bloods tests will need to be fasting (nothing but water or black, unsweetened coffee or tea for the eight hours prior to the visit).
- If you agree to participate in the optional metabolomics collection portion of this study, you will have an additional 4 teaspoons of blood withdrawn. In addition, approximately 5ml (2 teaspoons) of Urine will be collected for metabolomics.
- You will be asked to start a seizure calendar.
- You will be asked to begin to check your urine for ketones at home twice a week. You will be provided with urine ketones testing strips and you will be given instructions on how to perform the test. Urine ketones should be checked in the morning and we will ask you to record the time of day and the amount of ketones on

your calendar.
- You will be asked to start recording your weight weekly.
- You will be asked questions about symptoms caused by your disease or treatment.

You will also need to complete a standard 3-day diet record. This involves writing down all of the things that you eat and drink for 3 days. During this time you will continue to eat the same things that you have been eating and will record all of these foods and drinks. You will be asked to send the standard 3-day diet record to the study team as soon as you complete it.

Magnetic Resonance Imaging (MRI) of the Brain:

As part of your participation in this research study, you will have an MRI exam (or Magnetic Resonance Spectroscopy (MRS). The MRI exam will take approximately 60 minutes. Prior to your exam, you will be asked to complete a standard questionnaire. The purpose of this questionnaire is to ensure that you are able to safely enter the MRI area. If you have a history of metal in your head or eyes, you cannot take part in this study.

To start your MRI test, you will lie on a padded table. A Head/Neck Coil will be placed around your head, face, and neck. The coil is necessary to help the MRI machine take pictures. The table on which you are lying will be moved to the center of an MRI magnet, which looks like a long narrow tube. Even though the tube is open, some people feel confined in small places. If this bothers you, please notify the MRI staff. You may end your participation in this study at any time by telling the MRI staff. When MRI pictures are taken, or MRS is done, radio-signals and magnetic fields are used. When this happens, it is normal for the MRI machine to make loud, banging, and clicking noises. You will be asked to wear earplugs or headphones for your comfort during the exam.

During the exam, the MRI staff is able to see and hear you. You will be able to hear the MRI staff. The MRI staff will be talking to you throughout your MRI exam and may issue simple instructions regarding holding your breath, maintaining position, etc. You will generally be requested to lie perfectly still throughout the exam.

You will have two MRIs during this study: the first will be performed at the screening/baseline visit and the second will be performed at the 8 week follow-up visit.

Optional MRI

You also have the optional of an additional MRI at week 2 to see if the diet is already having an effect on the brain. This MRI at week 2 is optional. No matter what you decide to do, it will not affect your care in this study. If you decide now that you agree to have optional MRI performed, you can change your mind at any time. Please check if you are willing to have this optional MRI at week 2.

[ ] Yes [ ] No _____ Initials

GLAD Diet:
You will be on the GLAD diet for a total of eight weeks. Each week of the diet will be the same and will be divided into two types: on five of the days of the week you will follow a low carbohydrate, Modified Atkins diet, and on the other two days of the week you will fast.

During the fasting days you will not be able to eat anything except one ketogenic drink that will be provided to you and up to 2 cups of black, unsweetened coffee or tea. You will be required to drink at least 8 cups of water on your fasting days. At the beginning of the study, you will be able to select the two days of the week that you prefer to fast and these will remain constant throughout the 8 weeks that you are in this study.

On the five days that you are following the Modified Atkins Diet guidelines, your carbohydrates will be restricted to 20 grams per day. On days that you are fasting, you will be able to drink a high-fat, low carbohydrate liquid. You will be given a case of the drink which will last you the entire 8 weeks. You will be asked to drink one container on each fasting day in any manner and at any time that you choose. You may use it all at once or throughout the day. You can flavor it with approved sugar-free solutions, flavorings, Splenda or Stevia, or call the study team for other alternatives.

You will be offered a Modified Atkins Meal (prepared by the Metabolic Kitchen of the CRU) at your Baseline Visit as an example of the kind of meals you will be preparing for yourself.

You will leave all anti-epilepsy drugs unchanged throughout the 8 weeks that you are in this study. This is similar to previous studies that we have done with the Modified Atkins Diet.

Diet Records/Logs:
Throughout the study you will be asked to complete a diet record which is a hand written record of all of the food that you consume in the 24 hour period of time. You will be given instructions on how to do this. These records will be completed on the 3 days prior to each visit and for all fasting days during the week prior to the visit. You will do this 4 times over the course of the study. This will require that you accurately record ALL of the food and beverage that you eat and drink during this period of time.

Follow Up Visits:
You will come to the Clinical Research Unit at Wake Forest Baptist Medical Center for follow up visits every two weeks to meet with a registered dietitian and every month to meet with dietitian and the study doctor. The visits take approximately 1 – 1 ½ hours to complete.

During Week 2, Week 4, Week 6 and Week 8 (End of Study) Visits:

- We will check your weight.
- We will repeat a fasting blood test (approximately 2 tablespoons). For fasting blood tests please do not eat anything (except water or black, unsweetened coffee or tea) for the eight hours prior to the visit.
- You will be asked to continue to check your urine for ketones at home twice a week. We will ask you to record the amount of ketones and time of day the testing was performed on your calendar.
- We will record your seizures from your seizure calendar.
- We will review your diet records and see how difficult you find the diet.
- You will be asked questions about symptoms caused by your disease or treatment.
- If you agree to also participate in the optional MRI study at week 2, the Week 2 Visit and MRI occur on the same day the visit may take up to approximately 2 ½ - 3 hours to complete.

In addition to the above mentioned study assessments, during your Week 4 and Week 8 Visits, the study doctor will also assess your general health and neurologic function.

During the Week 8 (End of Study Visit) you will also have an MRI. The MRI takes approximately one hour to complete. If the Week 8 Visit and MRI occur on the same day the visit may take up to approximately 2 ½ - 3 hours to complete.

If you agree to participate in the optional metabolomics collection portion of this study, during the Week 8 study visit, you will have an additional 4 teaspoons of blood withdrawn. In addition, approximately 5ml (2 teaspoons) of Urine will be collected for metabolomics.

Follow Up Questionnaire:
We would like to contact you 6 months after your Week 8 (End of Study Visit) to ask you questions about what type of diet you have been following since your end of study visit. This can be done either by phone or e-mail.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

Optional Biospecimens Collection for Research

As part of this research study, we would like to ask you to let us collect additional biospecimens and health information for metabolomics research. Metabolomics is the study of the metabolic or nutritional health of cells, tissues, or organs.

As part of this research project, blood and urine samples will be de-identified (labeled only with a study ID and date of collection) and stored securely in a freezer only accessible by members of a study team until the end of the study, at which time they will be shipped to RTI International for the specified analysis. Samples will be analyzed in an effort to find out if there are metabolites that contribute to medical conditions that are part of this study. Because we do not know how the results of this testing relate to your individual health, the results of the research will not be given to you or your doctor without your permission. These results will also not be placed in your medical records.

RTI International

RTI International is an independent nonprofit company that collaborates with Wake Forest Baptist Comprehensive Cancer Center and the Proteomics and Metabolomics Core at Wake Forest on clinical trials involving metabolomics testing. Your samples will be sent to RTI International de-identified which means that no identifying information will be sent with it. All samples that are sent to RTI for metabolomics testing will be discarded after the testing is performed.

The research that may be performed with your blood and urine are not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your blood and urine will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood and urine samples will not affect your care.

Your blood and urine sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

If you agree to participate in the optional metabolomics collection portion of this study, you will have an additional 4 teaspoons of blood withdrawn during the Baseline/ Screening Visit and again during the Week 8 Visit. In addition, approximately 5ml (2 teaspoons) of Urine will be collected during the Baseline/ Screening Visit and Week 8 Visit for metabolomics testing.

Providing these samples is optional, if you choose not to provide these samples you can still participate in this study.

The study doctor can provide you with additional information if you have questions.

Will you allow us to use the additional biospecimens we collect for metabolomics research?

_____ (initials) **YES,** I agree to allow additional biospecimens (blood and urine samples) to be collected for use in metabolomics research

_____ (initials) **NO,** I do not agree to allow additional biospecimens (blood and urine samples) to be collected for use in metabolomics research

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 8 weeks.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. There may be side effects and discomforts that are not yet known. Risks and side effects related to the Modified Atkins Diet may include:

Possible Risks or Side Effects

- Worsening of seizures
- Fatigue, decreased energy
- Constipation
- Kidney stones
- Increased cholesterol
- Weight loss
- Feeling of hunger
- Low blood sugar

It is possible that you may experience one of these risks or side effects. While the Modified Atkins Diet has been used to treat seizures, it is possible that you may experience worsening of your seizures while on the GLAD diet.

Unlikely side effects

- Constipation

- Kidney stones
- Increased cholesterol
- Symptoms associated with developing low blood sugars (feeling lightheaded, dizzy, fatigued, passing out, and rarely confusion or seizures)

We will monitor you closely for these potential risks or side effects.

Rare but Serious Risks or Side Effects

- Kidney injury
- Heart attack or stroke

As the Modified Atkins Diet is a high-protein diet, there could be an unlikely risk of kidney injury, as the kidney would need to eliminate extra protein. This has generally not been a problem with the Modified Atkins Diet and has not been reported in other high protein diets.

There is a chance that if your cholesterol is elevated that you could be at risk for heart attack or stroke. This has not been observed with the Modified Atkins Diet but is a rare potential risk.

We will observe you closely and we will do lab studies to monitor for these potential risks.

Blood Draw: You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

Questions/Questionnaires: You may get tired or bored when we are asking you questions or you are completing a questionnaire. You do not have to answer any question that you do not want to answer.

Magnetic Resonance Imaging of the Brain: The effects of magnetic fields in an MRI scanner have been extensively studied, and there are no known significant risks with an MRI exam. You may, however, be bothered by feelings of confinement and noise made by the magnet during the procedure. You will be asked to wear earplugs or earphones while in the magnet. You may not participate in this study if you have a pacemaker, an implanted defibrillator, or certain other implanted electronic or metallic devices. It is important for you to advice the MRI staff if you have had brain surgery for a cerebral aneurysm or if you have implanted medical or metallic devices, shrapnel, or other metal, such as metal in your eye.

Incidental Findings: The MRI you are having as part of this research study will be reviewed by a qualified person just as it would be if you were having the MRI as part of your routine medical care. There is a possibility that while reviewing your MRI we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding." We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may

contact you by mail or by phone. In the case of a potential serious emergency, someone may go to your home. A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding. If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

Pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, a urine pregnancy test is required during the baseline/screening visit if you are a woman of childbearing potential. If you were to become pregnant, we would ask that the diet be stopped.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. If you benefit, you may find that your seizures occur less often. It is possible that your tumor may reduce in size; however, this is not currently known and will not be tested in this study.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. Your participation is entirely voluntary. If you do not participate, the care that you receive at Wake Forest Baptist Health will not be affected. You should talk to your doctor about all the choices you have.

Instead of being in this study, you have these options:
You can have other treatments for your brain tumor such as chemotherapy, radiation or surgery. These options depend on a discussion between you and your treating oncologist. In general, the risks of these alternative treatments are those that can be experienced with these standard of care treatments. These include but are not limited to bleeding, infection, new neurologic injury, low blood counts, skin irritation, hair loss, nausea, vomiting, fatigue, memory loss, and death.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

What About My Health Information?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

To ensure that your health information is kept confidential, you will be assigned a unique participant identification number. Your forms, records, scans, and samples associated with this

study will be labeled with this identification number; they will not be labeled with your name or any other personally identifying information.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3) Monitors, auditors, IRB or other regulatory or government agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

4) Investigators and study staff at the participating site, The Johns Hopkins Hospital, who are assisting with this research.

5) RTI International

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire and any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Roy Strowd that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Roy Strowd, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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 this Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH

medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

For your travel and other food and dietary expenses that may be related to this study, you will receive two $100 gift cards. The first $100 gift card will be given to you after your first study visit (Baseline/Screening visit). The second $100 gift card will be given to you after your mid-study visit (Week 4 visit).

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Science Department of Neurology, which is providing money or other support to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a

government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call *Roy Strowd, MD* at *3[redacted] this number can also be used during weekends and after-hours. Please ask for Adult Neurologist on-call if you call this phone number after hours.*

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. If you are taken out of the study early, we may use your health information that they have already collected if the information is needed for this study or any follow-up activities.

The investigators also have the right to stop your participation in the study at any time. This could be because:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- Your cholesterol or weight changes excessively.
- There may be other reasons to take you out of the study that we do not know at this time.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, *Roy Strowd, MD at [redacted], this number can also be used during weekends and after-hours. Please ask for Adult Neurologist on-call if you call this phone number after hours.*

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm