NORTH MISSISSIPPI HEALTH SERVICES
INFORMED CONSENT AND AUTHORIZATION FORM
(Use appropriate site/group title – example:
CARDIOLOGY ASSOCIATES RESEARCH, L.L.C.)

Study Title:

Principal Investigator:

Address and phone number:

Co- or Sub-Investigator(s):

Protocol Number:

Sponsor/Funding Agency:

What you should know about this research study is listed below.

- This consent form will help you understand the purpose, risks, and benefits of this research study.
- The main goal of standard treatment is to help the individual patient. It is based upon the best known treatment. The main goal of research studies is to gain knowledge that may help future patients.
- We cannot promise that this research will benefit you. As with standard treatment, this research can have side effects that can be serious or minor.
- Your participation in this study is voluntary. You may refuse to take part in this study. You may agree to take part now and change your mind later.
- Whatever you decide, it will not affect your regular care.
- Please read this consent form carefully. Ask any questions you have before you make a decision.
- This form will explain exactly what information about you is collected for this research study. It will also describe who will see this private information about your health.
- 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.

Why is this study being done?

You are being asked to take part in a research study of ***[state what is being studied]***. The purpose of this study is ***[state what the study is designed to discover or test (if the study is for an investigational drug, you should indicate that the study is to test effectiveness and safety of the drug)]***. You have been identified as a possible participant to take part in this study because ***[state why the subject was selected]***. ***[Include the approximate number of subjects in the study at NMHS and elsewhere.]***

What are the procedures and how long will this study last?
The study doctor will review your medical history, the results of your physical examination, and laboratory test results. The study doctor will then determine if you are eligible for the study. If you decide to take part, your time in the study will last approximately ____ days/months. You will undergo ***[describe the procedures to be followed, including the purposes of the procedures, how long they will take, and their frequency. In describing the procedures involved in the study, you should: list the standard treatment procedures; and list the procedures that will be done solely for the purposes of the study.***

Describe the randomization process in the following format:] You will be randomly assigned (like drawing a number from a hat) to one of ***[state number]*** treatment groups. Neither you nor your doctor will make the choice so that bias in the study is reduced. The ***[state number]*** groups are (a)... or (b)....

Your Responsibilities

If you decide to be in this study, you will have to:

- Keep all scheduled appointments.
- Take the medicine exactly the way your doctor tells you. Do not stop taking the medicine without first talking to Dr. _____ or a sub-investigator.
- Do not give the medicine to anyone else. Keep the medicine out of the reach of children.
- **Tell your doctor about any other medicines that you take, even if it is medicine you buy without a prescription. You should not take any other medication unless Dr. _____ or a sub-investigator says it is okay.**
- Tell your doctor about any medical problems you have or any changes in your health.
- Avoid becoming pregnant while on the study and for 30 days after you leave the study by using an effective method of birth control.
- Avoid breastfeeding while you are taking the study medicine.
- Return your medicine containers to Dr. _____ or a sub-investigator at each visit.
- Tell Dr. _____ or a sub-investigator if you want to stop being in the study.
- **If you do not follow the items listed above, you may be removed from the study.**

What are the risks and discomforts?
[Describe reasonably foreseeable risks, discomforts or inconveniences to the subject - including health, legal, economic and psychological risks
Use the following terms and numbers to describe the likelihood of an adverse event.

- "likely" events are expected to happen to more than 50% of subjects,
- "frequent" events will probably happen to 10 to 50% of subjects,
- "occasional" events will happen to 1 to 10%, and
- "infrequent" events will happen to less than 1%.

[Describe the randomization of risks as follows:]
You will be assigned to a treatment program by chance. The treatment you receive may be less effective or have more side effects than the other study treatment or than other available

treatments. This will not be known until after the study is completed and the data have been analyzed.

[State and explain risks, if any, to pregnant women or women of childbearing potential. If the risk is significant, add the following section:]

What are the risks to pregnant women?

This research represents a significant risk to unborn children. Therefore, if you are a woman who might become pregnant, you will be given a pregnancy test prior to the beginning of the study.

If you are not pregnant, you will be offered information on birth control methods ***(may need to provide specific examples)*** to be used during the study to avoid pregnancy. You will also be advised as to the danger to the fetus should you become pregnant.

Are there any unexpected risks?

There is always the possibility that you may have a reaction or side effect that is currently not expected. It is important that you report any reactions to your study doctor. You will be monitored for side effects by study personnel and, if indicated, will be withdrawn from the study.

What are the benefits of being in the study?

[Describe any benefits to the subject or to others which may reasonably be expected for the research.]

[Clearly state if the benefit is expected to be primarily for others].

Example: The benefits from your participation in this study include the possibility of ***[state the intended goal (lowering blood pressure, controlling pain)]***. We do not guarantee, or promise that you will receive any benefits from this study. Your participation in this study will contribute to information about ***[state drug, device, condition]*** and may benefit other patients with [***state condition]***.

Are alternative treatments or procedures available?

[Indicate appropriate alternative procedures or courses of treatment which may be advantageous to the subject, if any treatment is required. Any standard treatment that is being withheld must be disclosed. Include a statement that one alternative is no further therapy. IF APPLICABLE, state that a potential participant will receive standard care whether or not s/he participates in the research study.]

Example: If you decide not to participate in this study, there are other therapies currently available such as ***[list options as noted above]***.

Will I be informed of any new findings?

You will be informed of any new findings that may influence your desire to continue participation in this study.

What are the costs?
Example: There will be no charge to you for the study medication and any of the office visits, procedures, and laboratory tests associated with the study drug.

Are there any additional costs?
[Specify what costs are borne by the study and which are the responsibility of the subject. If there is a possibility of additional costs to the subject because of participation, this should be disclosed.]
Example #1: The drug itself will be provided at no cost. You (or your health care insurance carrier) will be responsible for any charges relating to the preparation or administration of the drug. The costs of monitoring (blood tests, chest x-rays, etc.) necessary will also be your responsibility. Some health care insurers do not allow coverage for investigational drugs. If this is of concern to you, you should check with your health care insurer.

Example #2: The study drug will be provided free of charge, and you will not be billed for tests required for purposes of research, (provide study-specific example). . You or your insurance company will be billed for your hospital stay, and all standard laboratory tests (e.g., routine blood counts and blood chemistry tests) that are unrelated to the study drug.

Example #3: Neither you nor your insurance carrier will be charged for any of the study treatments or procedures. Costs of the drug treatment and the other tests will be covered during the study period of (specify time). If treatment is to continue thereafter, other arrangements must be made to cover its cost.

Will I be paid for the study?
[Money may be offered to reimburse expenses, time, inconvenience and transportation. However, money may not be used as an inducement to assume risk. IF the payment to the participant will be pro-rated based on how much of the study the participant completes, that must be stated and the method of pro-rating explained.]

Example: You will be paid for the miles you travel to the clinic, based on the current government mileage rates. You will need to provide your round trip mileage (from your home to the clinic) at your first clinic follow-up visit.

[ADD the following statement TO ALL CONSENT FORMS FOR INDUSTRY-INITIATED, FIXED-PRICE CLINICAL TRIAL AGREEMENTS.] In addition, the study sponsor will pay the researchers for their time and effort.

What if I get sick or hurt?
If you experience any bad effects or injury during the trial, you should immediately contact ***[list principal investigator and provide 24-hour access phone number]***. If you seek emergency care or hospitalization is required, please inform the treating physician that you are enrolled in a research study being conducted by ***[primary investigator's name]***. If you are injured from your participation in this study, you should obtain medical care in the same way as you usually obtain medical treatment. You should understand that the costs of such treatment will be your

responsibility. Financial compensation is not available. ***[If the sponsoring agency has made a provision for payment of emergency medical treatment, then you may omit the last two sentences and provide the information as follows in the next section.]***

Will I be compensated if I get sick or hurt?
Example: If you suffer a physical injury as a result of receiving the investigational study drug or treatment, you will be reimbursed for reasonable and customary medical expenses that result from treatment of such injury. You will be reimbursed for the expenses not covered by your insurance or governmental coverage. Medical expenses will not be reimbursed if your injury is due to your failure to follow instructions contained in this consent form. You will not receive financial payments for losses (such as lost wages, lost time from work, or discomfort), with respect to such injuries. You do not give up any of your legal rights as a research subject by signing this consent form ***(must be included on every informed consent form)***.

Can I leave the study after it has begun?
Your choice to take part in this study is voluntary. If you decide not to take part or decide to withdraw from the study, you will not be penalized or lose any of your regular benefits. You may stop taking part at any time without affecting your ongoing medical care. It is your responsibility to notify the study doctors of your decision to withdraw from the study.

Your study doctor may end your participation in this research study without your consent for any of the reasons below.

- If you experience an adverse event or medical condition that could place you at risk of further complications if you continue your participation.
- If you are unable to take the study medication.
- If you are unable to keep your scheduled appointments.

What if I have a question or problem?
You may freely ask questions about this consent form or the study, now or at any time during the study. If you have any questions about this study, or believe you have had an injury or bad reaction due to your participation, please contact ***[list principal investigator and 24-hour phone number]***. If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research- related injuries, please feel free to contact Grant Smith, PharmD, Manager of the North Mississippi Health Services, Institutional Review Board at 662-377-8693. **A copy of this consent form will be given to you.**

What Happens if I Leave the Study Early?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new information about you will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. ***[Any other information with regard to contact with or collection of further data from the patient after withdrawal from the study that is stated in the protocol may need to be added here].*** If such an adverse event occurs, we may need to review your entire medical record. All information that has already been collected for study purposes, and any new

information about an adverse event related to the study, will be sent to the study sponsor and the Clinical and Data Coordinating Centers.

Authorization to Use and Disclose Health Information
A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you.

Who will Use and Disclose My Health Information?
Participation in research will cause a loss of privacy, but your personal health information will be kept as confidential as possible. Your study doctor, representatives of the sponsor ***[state name],*** the sponsor's agent ***[state name],*** the Food and Drug Administration (FDA), and the Institutional Review Board of North Mississippi Health Services may review information about you to check on the study. Your personal health information will be used in accordance with federal and state law. Your name will not be used in any published reports about this study.

[Site name] utilizes an electronic medical record system called EPIC. The EPIC system is utilized by North Mississippi Health Service's physicians and employees and private physician groups in the area. These physicians and employees may access your health information in EPIC for treatment, payment or healthcare operations.

What Health Information will be Used and Disclosed?
Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except as addressed in this authorization form, you will not be identified by name, social security number, address, telephone number, or any other form of personal identification in study records shared outside of ***[site name]***. For records shared outside of ***[site name]***, you will be assigned a unique code number. The key to the code will be kept in a locked file in ***[principal investigator]*** office. These groups will also be in compliance with the Federal Privacy Regulations.

This information may be further shared by the sponsor of this study, ***[name of sponsor]***. If shared by the sponsor, the information is no longer covered by the federal privacy regulations.

If these data are used by any other research organization, additional steps will be taken to first remove all private health information.

Who will Receive My Health Information?
Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the following.

- representatives of ***(list the appropriate groups)***
- Food and Drug Administration
- National Institutes of Health
- Clinical Coordinating Centers

- Data Coordinating Center
- Data Safety Monitoring Board
- North Mississippi Health Services Institutional Review Board

If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

Will My Authorization Ever Expire?
Your authorization (permission) to use and share your Authorized Health Information will continue for _____ years/indefinitely. The use and sharing of your information will only be for the purposes described in this consent form.

May I Take Back My Authorization?
You have the right to take back (revoke) your authorization at any time by writing to [***site name (attention: study doctor), address].***

If you revoke your authorization, the study team will not collect any new health information about you. However, they can continue to use and share any already collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your authorization, you can no longer continue to participate in the study.

May I Look at My Study Information?
You have a right to see and make copies of your medical records. However, to make sure the results of the study are reliable, you will need to wait to see your study records until the study is completed.

Specific Understandings
[Site name}, staff members and physicians who are performing this research will use and share your information only as described earlier. However, once it is shared with others for research purposes, ***[site name]*** cannot directly control their future uses and sharing of your information. For this reason, ***[site name]*** has requested that the research sponsor and its agents use your information only for this research and not for other purposes.

Important
You are making a decision whether or not to participate in this study. Your signature indicates that you have done the following.
- read and understood the information provided above,
- asked the treating physician any questions you may have had,
- had all your concerns addressed by your physician,
- and have decided to participate.

Each page of this Informed Consent Form is stamped to indicate the form has been approved by the North Mississippi Health Services, Institutional Review Board (IRB).

Subject Statement
I have read, or have had read to me, and understand this consent form and my questions have been answered by my doctor. The purpose of the research, the study procedures that I will undergo, and the possible risks and discomforts as well as the benefits that I may experience have been explained to me. Alternatives to my participation have also been discussed. Therefore, I voluntarily agree to consent to participate in this research study.

_____
Name of Subject (please print)

_____ _____
Signature of Subject Date / Time

By participating in this clinical trial, I understand and authorize my physician, ***[name]*** the sponsor ***[name]***, the FDA, the NMHS IRB and North Mississippi Medical Center personnel to have access to my medical record's protected health information for the purpose of clinical research and to use my protected health information in accordance with federal and state law.

_____
Name of Subject (please print)

_____ _____
Signature of Subject Date / Time

_____ _____
Signature of Person Obtaining Consent Date / Time

Investigator's Statement
I have given all/pertinent research study information to this research subject. In my opinion, this study information is accurate and sufficient for the subject to fully understand the nature, risks and benefits of the study, as well as the rights of a research subject. I represent that there has been no coercion or undue influence.

_____ _____
Investigator's Signature Date

Legal Representative Consent

The person being considered for this study is unable to provide written consent for himself/herself. I as legal representative have been explained the risks and benefits of the procedure and device/drug study. All my questions regarding the procedure and device/drug study have been answered, taking into account my understanding of the subject's view on treatment. I hereby consent to the procedure and device/drug study.

_____ _____

Legally authorized representative (please print) Date / Time

_____

Legally authorized representative (signature)

Reason subject cannot consent for self:_____

_____

_____

Relationship to the Subject: please check the description which fits the consenting person the best.

- ☐ Legally appointed guardian
- ☐ Subject advocate named in "Durable Power of Attorney for Health Care"
- ☐ Spouse
- ☐ Adult son or daughter
- ☐ Parent or adult
- ☐ Adult brother or sister

WITNESS STATEMENT

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject and/or the subject's legally authorized representative. The subject and/or the subject's legally authorized representative freely consented to participate in the research study.

Witness (please print) Date / Time

Witness (signature)