MEMORIAL HEALTH UNIVERSITY MEDICAL CENTER

Consent for Participation in a Research Study

[Remove all instructional text and red color-coding from this document once complete.]

TITLE: [insert title of research study here]

SPONSOR: [insert study sponsor if applicable, delete if not applicable]

PRINCIPAL INVESTIGATOR: [insert name of principal investigator]

SUB INVESTIGATORS: [insert name of sub investigator(s)]

PHONE NUMBER: [insert contact information for primary investigator]

24 HOUR NUMBER: [insert 24 hour contact information for appropriate investigator]

MEMORIAL UNIVERSITY MEDICAL CENTER CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

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("I" or "You" refers to the person participating in the study).

Why are you being invited to take part in a research study?

You are being asked to participate in a research study because [provide clear information as to why subjects are being asked to enroll, ie. You are being asked to participate because you are between the ages of 15 and 65 and have diabetes.]. Your participation is voluntary. Your decision whether or not to participate will not affect the quality of medical care you receive. If you join the study, you can stop or leave at any time with no changes in the quality of the health care you receive. You will be told about any new information or changes in the study that could affect you.

Please ask questions if there is anything you do not understand.

PURPOSE OF STUDY

The purpose of this study is to learn about [Tell the subject the purpose of the research using everyday language that is easy to read and understand. Explain the background of the research problem. Include a description of the experimental drug, device, or procedure if applicable. If the drug/device is not FDA approved for use as mentioned in this study, make this completely clear and be sure to use the word "experimental" or "investigational." If this study is posted on clinicaltrials.gov, include a link to the study site.]

You may or may not benefit from being in this research study. We hope to gather information that may help people in the future.

DESCRIPTION OF STUDY PROCEDURES

Approximately [number of expected participants] subjects will participate in this research study at Memorial Health University Medical Center. Your participation in this study is expected to last [length of time, example: approximately one hour, twice a week for one month].

[Provide description of every visit, including but not limited to: blood draws, EKGs, injections, follow-up visits, pulmonary function testing, x-rays, questionnaires, and all other procedures involved in the study.]

[Modify as needed] Clearly describe:

- whether or not the drugs/devices being used are in ways that are non-FDA approved;
- If no drugs or devices being used, describe the questionnaire or procedure that is the basis for the research: for example: Quality of Life survey, measuring the blood pressure at different times, taking out a Foley catheter at a different time than standard of care.
- Process of randomization (How the decision is made what the patient will be assigned to: “like the flip of a coin” if chances are 50/50, “by chance,” “like the roll of a dice,” etc.); if applicable
- Use of placebo (“inactive substance,” “sugar pill,” etc.)if applicable
- Whether or not all participants will receive the same therapy, and if not, the probability of receiving study drug vs. placebo
- Dosage of study drug and the probability of random assignment to placebo or to treatment arms (e.g., if you are randomized to receive study drug XXX, you will receive one of the following doses: 300 mg per day or 600 mg per day;
- Process of Blinding (“neither you nor the study doctor will know which treatment you receive; in the event of an emergency, your study doctor can determine which drug or procedure you are receiving.”)
- Procedures that are considered to be experimental rather than standard of care.

POTENTIAL RISKS/DISCOMFORTS

[Provide description of potential risks and discomforts in lay terms.To include for example: Blood Draw- bruising at site of blood draw, pain, possibility of infection, a reaction to the gel used for the ultrasound – redness, irritation Physical risks, Psychological risks, Privacy risks, Legal risks, ocial risks, Economic risks, Risk, if any, of receiving no treatment if there is a placebo arm]

[If appropriate to your study] We cannot be sure how your body may respond to the [medications or procedures] used in this study. The researchers will discuss possible difficulties and that chances that they will happen.

[If appropriate to your study] There may be risks or side effects related to the study drug/procedure that are unknown at this time. You will be notified of any significant new findings that may affect your willingness to continue in the study.

For breach of confidentiality: [The only risk/One of the risks] of being in this study is that your personal information could be lost or exposed. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected.

REPRODUCTIVE RISKS

[Include reproductive risks, if applicable] There may be unforeseen risks to an unborn child associated with your taking [insert drug name]. For this reason, you must agree to use a highly effective means of birth control, such as hormonal contraceptives, intrauterine device (IUD), an implantable contraceptive (such as Norplant), an injectable contraceptive (Depo-Provera), a barrier method of contraception (such as a condom or diaphragm with spermicide), or abstinence. You should discuss your methods of birth control with the study doctor. You must notify the study doctor if you suspect that you may be pregnant or if you are a male and suspect that your partner may be pregnant. The effects of drug XXX on a nursing infant are unknown. If you are breastfeeding, you cannot participate in the study.

[Include this section if you need to educate the research subject about potential health and safety implications of a research intervention.] If you take part in the research, it is important for your safety that you:

- Follow the directions of the study doctor and research staff.
- Tell your other health care providers that you are in a research study.
- Tell your study doctor and staff about all medications you are taking (prescription and over the counter) and all of your health issues.
- Call the study doctor or staff at _____ [provide contact number] if you have any questions.

POTENTIAL BENEFITS [Explain whether there are any direct benefits to the subject.] Participation in this study may help to improve your condition, but it is also possible that your condition may worsen. There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help other people who have a similar medical problem in the future.

EXAMPLE:

No, the results of the study may help others in the future, but there is no direct benefit to you.

EXAMPLE:

This study may not help you in any way either because the study drug/device does not work or because you are in the placebo group. However, the results of the study may help others in the future.

TREATMENT ALTERNATIVES
You do not have to participate in this research study to receive treatment for your condition. You may choose not to be in this study. This will not jeopardize your care in any way. There are other ways to treat your condition. The study doctor will discuss alternative treatments with you.

[If appropriate, inform subjects that there are no alternatives other than not participating. There may be alternative palliative treatments that are not curative. This information should be shared with the subject.]

[If the drug used in the study is FDA-approved, subjects should be informed that the study drug is commercially available and that they do not have to participate in the research study to have access to the agent under study.]

[If this is a survey, questionnaire –the only alternative is to not participate.]

CONFIDENTIALITY
Your medical records will be kept as confidential as possible within the limitations of state and federal law. Federal Privacy Regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use of disclose your individually identifiable health information may include the study doctor, the study staff, Memorial Health University Medical Center [is both institution and sponsor for original research], and [list all applicable parties].

In order to analyze the data collected during this research study, all of the health information generated or collected about you during the study may be inspected by Memorial Health University Medical Center's staff involved with the study [indicate study sponsor or the authorized agents of the sponsor – list if not Memorial], the Federal Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) agencies, the Memorial Health University Medical Center's Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects), [list other parties as appropriate]. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. Once your personal health information is released it may be redisclosed, at which point your health information will no longer be protected by federal privacy regulations.

The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations. By signing this informed consent form, you are authorizing such access to your medical records. This authorization will have no expiration. [Or this authorization will expire on --/--/--.]

Will being in this study cost me any money?

[Include clear language regarding what costs might be incurred by the research participant. If all costs are paid by a sponsor, say that specifically. If there are some

charges that might go to insurance or be the research participant's responsibility, note that and the possibility of co-pay and/or deductibles.]

EXAMPLE:

No.

[If applicable] You will not be paid to be a part of this study.

EXAMPLE:

You or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

[If this study involves the use of an experimental drug or agent, add the following language] (Drug name or agent) will be provided to you at no cost; however, you or your insurance may be billed for the administration of this drug or agent.

COMPENSATION FOR INJURY

If you suffer an injury as a result of your participation in this study, Memorial Health University Medical Center [or appropriate Sponsor] will provide the necessary treatment for such injury, but you, your insurance company or a government program will be billed for the treatment. No other compensation will be offered by Memorial Health University Medical Center. You are not waiving any legal rights by signing this form.
[If this is sponsored by a grant, pharmaceutical company, or a device company, the terms of the contract for compensation must be added here].

QUESTIONS ABOUT THE STUDY

If you have any questions concerning your participation in this study, or if you feel you have experienced a research-related injury [or a reaction to the study medication, if applicable] you should contact the study doctor, [insert PI's name and phone number and/or other appropriate contact with phone number]. This is a 24-hour number in case of research-related emergencies that may occur after normal business hours.

If you have any questions about your rights as a research subject, you may contact:

Memorial Health University Medical Center's Institutional Review Board
Dr. Richard Leighton, Chair
4700 Waters Avenue
Savannah, GA 31403
(912) 350-6866

The Institutional Review Board is a committee that monitors the safety and welfare of research subjects at Memorial Health University Medical Center.

PARTICIPATION/AUTHORIZATION

Your participation in this research study is voluntary. You have the right to decline participation or to withdraw from this study at any time. This will in no way affect your current or future medical care. If you decide to withdraw from this research study, you must inform the study doctor. [If applicable, study drug is given] For safety reasons, you will be asked to return to the clinic for a final study visit.

You may also decide to take away your permission to use or disclose personal information about your health. If you choose to withdraw your permission, you must notify the study doctor in writing. The study doctor's mailing address is [include study doctor's complete mailing address and telephone number]. The study doctor will still be able to use the information collected about you prior to your withdrawal from the study. Information that has already been sent to the study sponsor cannot be withdrawn.

[This section, if applicable should be added for drug study or a study that has more than one visit] Your participation in this study may be discontinued without your consent by the study doctor or the sponsor [list] if you fail to follow study instructions. You may also be withdrawn from the study if, in the study doctor's or sponsor's opinion, the study drug is ineffective, harmful, or has medically unacceptable side effects, or for other reasons at the discretion of the study doctor or sponsor. [If appropriate, add] If you are withdrawn from the study, you will be asked to have the appropriate medical tests and follow-up to evaluate your health and safety.

COSTS

[Identify costs, if applicable, that are standard of care and those that are paid for by the study] [If there is no cost, please indicate that there is no cost].
Example: The study medication will be supplied at no cost to you. Any tests, examinations, or other procedures that are done solely for research purposes as previously described will be paid for by the sponsor*[Memorial, if original]* of this study. Insurance companies or other third party payers will not be billed for the above listed research procedures.

The rest of the medical care that you will receive in this study is considered standard of care for your condition and thus would be recommended regardless of your decision to participate in research. These costs will be billed to you or your insurance or governmental agency.

[Use appropriate wording as applicable to study.]

[If there is reimbursement for subject's travel expenses or any other compensation, the dollar amount should be clearly defined and an explanation if there is payment scale, if any, should be made clear; e.g., "You will be

reimbursed a maximum of $150 for your participation in this study to help offset the cost of your time and travel to the study doctor's office. If your participation in the study ends prior to study completion, you will be reimbursed $25 for each study visit you completed."]

CONFLICT OF INTEREST

Conflict of interest means a situation in which a member of the local research team for this study, including the study doctors, and study coordinator(s), has a significant financial interest or other personal involvement that may compromise, or have the appearance of compromising, his or her professional judgment or integrity in conducting this study. No member of the local research team has a conflict of interest for this study**.** [If a conflict exists state it here].

STATEMENT OF CONSENT

I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. By signing this form, I voluntarily consent to participate in the research study.

Unless I authorize the use and disclosure of my personal health information, I cannot participate in this research study. If I refuse to give my authorization, my medical care will not be affected.

I have received a copy of this consent form for my records.

Printed Name of Subject	Signature of Subject	Date
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date
Printed Name of Witness, if required	Signature of Witness	Date
Printed Name of Subject's Legally Authorized Representative, if required	Signature of Subject's Legally Authorized Representative	Date