Informed Consent Form – Blood Sugar Control in Stroke

You have had a stroke, and your blood sugar is high. You are being asked to participate in a research study about how doctors treat high blood sugar in patients with stroke.

You are an appropriate candidate for this study, but you do not have to be in it. **It is your choice. Either way you will be treated with the highest quality care.** If you do decide to take part in the study, you can stop participating at any time. This form tells you about the study. Please ask questions about anything that is not clear.

Please let us know if you have *type 1* diabetes, are pregnant or breast feeding, or are on dialysis. If so, you should not be included in this study.

What is the study about?

This study is about how doctors control blood sugar during the first few days of treatment for stroke. Studies have shown that high blood sugar during this time may be bad for brain recovery, but doctors do not know what level of blood sugar is best.

How is this different from what would be done normally?

The standard way to treat blood sugar during the first few days after a stroke is to use insulin to keep blood sugar from getting very high. This study is designed to find out whether keeping the blood sugar in a more normal range (80-130) is better than the standard approach of not letting it get very high (keeping it under 180).

In this study, patients in the lower blood sugar group (130-180) will be given insulin by IV. Patients in the standard blood sugar group (under 180) will be given insulin shots under the skin. In both groups, blood sugar will be regularly checked using blood from a finger prick.

Patients will not know which group they are in, and neither will their doctors. Patients in the lower blood sugar group will get insulin through an IV and salt water shots under the skin. Patients in the standard blood sugar group will get insulin shots under the skin and salt water through an IV. This ensures that all patients are treated alike in other ways.

How is it decided which group you will be in?

A computer will randomly assign you to be in one treatment group or another. *You will have an equal (50/50) chance of being in either group.* Your doctor will <u>not</u> make this choice.

What will be required of you?

In the hospital- Being in this study only affects treatment of your blood sugar during the first 3 days after your stroke. You will also have physical exams to assess stroke symptoms, and the study team will record information about your stroke treatment from your medical record.

After you leave the hospital- You will receive one follow-up phone call and be required to come in for one follow-up office visit 3 months after your stroke. Please see the accompanying study information sheet for more details.

What are the possible benefits of being in the study?

The main goal of this study is to improve care for patients with stroke and high blood sugar. Your participation may help to improve treatment for stroke in the future. It is possible that patients in one of the two blood sugar groups will have better outcomes. However, doctors do not currently know which way to treat blood sugar is better.

What are the possible risks of being in the study?

The main risk of this study is low blood sugar. This is a risk of treating high blood sugar with insulin in general. Having low blood sugar can make people feel bad. If your blood sugar stays very low for a long time, this can be serious and can lead to seizures or even death. Serious side effects like these are extremely rare. Researchers will minimize this risk of low blood sugar by monitoring your blood sugar carefully and treating it if it gets low. A complete list of risks can be found in the study information sheet.

What is the alternative to being in the study?

The alternative to being in the study is simply to have your blood sugar managed according to the standard protocol at this hospital.

What happens if you are harmed by being in the study?

If you get ill or injured from being in the study, Emory/Grady will help you to get medical treatment. Your insurance company will be billed for costs of your care. If you do not have insurance, or if your insurer does not cover treatment, then you will be responsible for these costs, like other costs of treatment. The only exception is if it is proved that your injury or illness was directly caused by an Emory/Grady employee who is negligent by not following the standard of care. For additional information, please see the study information sheet.

Will insurance cover treatment in the study?

There will be no extra charges for being in this study. Payment for treatment will be handled the same as if you were not in the study, according to the terms of your health insurance policy.

Will you be paid for being in the study?

You will not be paid for being in this study, but your transportation costs for the follow-up visit will be covered.

Will your information be kept private?

Your information will be kept private in accordance with research regulations. We use a special code to identify your information, and we will not identify you in research reports. However, your records may be reviewed by study sponsors or FDA, as allowed by research regulations.

See the study information sheet for details on privacy rules and procedures if you have questions.

What can you expect from the researchers?

If at any time the researchers find out about unexpected risks or dangers to you or others in the study, they will inform you and may remove you from the study if needed, in accordance with standard medical practice. They will also honor any decision you may make to withdraw from the study at any time. Your medical care will not be compromised in any way.

Whom can you contact if you have questions or concerns?

You can contact the study doctor (_____), study team (_____), or the research review board (_____) at any time if you have questions or concerns.

A description of this study is available on http://www.ClinicalTrials.gov. This website does not identify patients. At most, it will include a summary of the results. You can search this website at any time.

Consent

Please **print** your name, **sign**, and **date** below if you agree to be in the study. By signing this consent and authorization form, you will not give up any of your legal rights.

_____

Name of Participant

Signature of Participant (18 or older and able to consent) **Date** **Time**

Signature of Legally Authorized Representative with authority for research decisions **Date** **Time**

Relationship to Participant or Authority of Legally Authorized Representative

Phone number for Legally Authorized Representative

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Consent Discussion **Date** **Time**