INSTITUTION NAME

Consent To Be Part Of A Research Study

### Information About tHIS form

You, or your family member, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Legally authorized representatives who are giving permission for a family member, please note: in the sections that follow the word “you” refers to your family member.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

### 1. General Information About This Study AND the RESEARCHERS

## 1.1 Study title: Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

## 1.2 Company or agency sponsoring the study: This study is sponsored by the University of Virginia and funded by the National Institutes of Health – National Institute of Neurological Disorders and Stroke (NIH-NINDS).

## 1.3 Names, degrees, and affiliations of the researchers conducting the study:

Include local PI, local Co-Is

### 2. PURPOSE OF THis STUDY

## 2.1 Study purpose:

## Laboratory and human studies have shown that high blood sugar levels during a stroke can be associated with more damage to the brain than normal blood sugar levels. Blood sugar levels can be lowered with a hormone called insulin, which can either be given as a shot under your skin (subcutaneously) or into a vein in your arm through a tube called an IV.

## The purpose of this research study is to find out if treating high blood sugar in stroke patients with IV insulin shows better recoveries than the current standard care for treating high blood sugar.

## IV insulin for blood sugar control has been shown to be a safe treatment in previous studies of acute stroke patients. The next step is to learn if this treatment can improve recovery after stroke.

### 3. Information About STUDY participants (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

## 3.1 Who can take part in this study?

To participate in this study, you must:

* Have recently had a stroke caused by a blood clot in your brain
* Have either:
	+ a history of type 2 diabetes and a blood sugar level above 110 mg/dL,

**or**

* + no history of type 2 diabetes and a blood sugar level at or above 150 mg/dL
* Be over 18 years old
* Be able to start treatment within 12 hours of the start of your stroke symptoms or the last time you were known to be well Have had no significant disability before your stroke
* Meet all study inclusion and exclusion criteria

Please tell the study doctor if you have any of the following:

* Any history of type 1 diabetes
* Any history of severe neurological or psychiatric illness
* Current pregnancy or currently breast feeding
* Current kidney dialysis treatment

If you have any of the conditions listed above, you will not be able to participate in this study because it may not be safe for you.

## 3.2 How many people (subjects) are expected to take part in this study?

About 1400 stroke patients are expected to take part in this study at about 65 medical facilities around the country. You will be one of \_\_\_\_\_\_\_\_ enrolled at \_\_\_\_\_\_\_\_\_\_\_\_\_ Hospital.

### 4. information about study participation

**4.1 What will happen to me in this study?**

Baseline and Enrollment Procedures

You will be given a full medical and neurological exam, including a CT scan which takes a picture of your brain, baseline blood pressure, blood tests, and electrocardiogram (ECG). Though these are all part of standard care for stroke patients, we also record the results for the study. The study will also record information about your age, gender, and ethnic origin.

The study will use random assignment (like the flip of a coin) to place each patient into one of two groups. One group will be given IV insulin and subcutaneous insulin shots to control high blood sugar. The other group will be given standard subcutaneous insulin shots to control high blood sugar. Both groups will be getting IV solutions and subcutaneous shots so that you will not be able to tell which group you are in.

As the trial goes on, your chance of being placed in one treatment group or the other will be based on the recovery of the patients enrolled before you. At the time you are randomized, if one treatment group is doing better than the other group then you will have a better chance of being placed in the group with the patients who have had better recovery.

Study Activities - First 3 Days in Hospital

During the first 3 days, you will receive medical and neurological exams at least once a day. These are standard care for stroke patients. In addition to these exams, a special neurological exam (National Institutes of Health Stroke Scale - NIHSS) will be done at the beginning of the study, each of the first 3 days of the study and/or at the end of the treatment if you are ready to be discharged from the hospital earlier than the third day. The NIHSS will also be done if at any time your symptoms should worsen during the first 3 days.

An IV catheter will be placed in your arm for the IV study solution. During the first 3 days in the hospital, you will receive both an IV study solution (approximately 1 teaspoon per hour consisting of either insulin or sterile salt water) and up to four subcutaneous shots per day (about 1-4 drops of either insulin or sterile salt water) based on the study insulin dosage plan. You will have your blood sugar level checked by a finger stick about every hour for the first four hours and then about every 1-3 hours. IV solutions or subcutaneous shots will be adjusted by your nurse to keep your blood sugar at the right levels.

As part of your hospital stay, you should expect about 6 finger stick checks per day as part of your standard care. Extra finger stick checks will be done as part of the study. In total you should expect about 8-20 checks per day as this is required for the safe management of insulin therapy. If your sugars are easy to control you may receive fewer checks, or if difficult, more checks per day may be needed.

For the first 3 days during study treatment in the hospital, you will not be allowed to take any other medicines to lower your blood sugar, such as pills you may usually take for diabetes, that are not part of the study treatments. You will also need to follow a special study diet during this time, and will be allowed to have only study-approved snacks. At the end of the first 3 days of the study or before leaving the hospital, whichever comes first, the plan to restart your home medicines for high blood sugar or to start a new treatment program will be decided between you and your treating doctor and is not part of this research study.

Study Activities – 6-week Interview

You will receive a telephone call from the study team about 6 weeks after your stroke that will last about 20 minutes. You will be asked about any new symptoms or illnesses, what medicines you are taking, how your recovery is going and how well you are able to do regular daily activities. If you are not able to speak on the phone, we may ask a family member or caregiver questions about how you are doing.

Study Activities – 3-month Visit

You will see a study doctor and/or study nurse, who has special interest and training in caring for stroke patients, about 3 months after your stroke. During this outpatient follow-up visit at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, you will be given a neurological exam including the NIH Stroke Scale. You will also be asked a series of questions that will measure how well you have recovered in your physical, thinking, and speaking abilities and how much help you need (if any) with usual daily activities. You will also be asked about your general quality of life and recovery using standard scales with simple questions which are answered by you and/or your family members (in case their help is needed). You will be asked what medications you are currently taking and whether you have had any serious illness or any hospitalizations since the 6-week telephone interview.

If for some reason we are unable to locate you for the 3 month follow up visit, we will employ an people locating service to help us locate you. The firm will not have access to your health records or study results, but will be able to access other personal information such as phone number, address, etc. We will keep all records that we produce private to the extent we are required to do so by law.

## 4.2 How much of my time will be needed to take part in this study?

Neurological examinations, including the study-related NIH Stroke Scale, will take 5-15 minutes each. Each blood sugar check will take less than one minute, approximately 8-20 times per day for 3 days. The 6-week phone call will take approximately 20 minutes, and the 3-month visit will take approximately two hours.

## 4.3 When will my participation in the study be over?

Your participation in the study will be over about 3 months after your stroke.

### 5. information about RISKS and benefits

## 5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

* Low blood sugar. If your blood sugar is low enough, you might feel:
	+ Confused
	+ Nervous
	+ Hungry
	+ Tingly or weak or
	+ Show signs like fast heart rate, sweatiness, sleepiness.

Your nurse will ask you about these and record them in case your blood sugar is low, but you should also report these feelings to your nurse if you are having them because they can mean your blood sugar may be low and needs to be checked. If your blood sugar stays very low for a long time, this can be serious and result in worsened neurological symptoms, seizures or even death, though this is extremely rare. If your blood sugar goes low but is brought back to normal quickly it is unlikely to result in injury.

The researchers will try to minimize this risk in these ways:

* + Your blood sugar levels will be checked frequently to prevent low blood sugar from occurring.
	+ If you have a finger stick blood sugar of less than 80, the study drug infusion will be temporarily stopped and you will be given glucose (sugar) therapy right away so that your blood sugar will not go too low.
	+ Your blood sugar level will be checked every 15 minutes until your blood sugar level reaches at least 80 mg/dL. The study drug infusion will be restarted when it is safe to do so.
* Problems associated with blood drawing, finger stick blood sugar checks, and IV placement:
	+ Pain from inserting a needle under the skin surface (common)
	+ Fainting at or about the time of blood drawing (infrequent)
	+ Bruising at the site (infrequent)
	+ Infection at the site (rare).

To allow the study IV solution to be given safely and adequately, during this study, you may occasionally need to have the first IV catheter replaced.

* There is a slight risk that your personal information may be accidentally released for reasons other than the ones listed in Section 9 below. The researchers will try to minimize this risk by handling your information carefully, storing it securely, and sharing it only with authorized persons.

As with any research study, there may be additional risks that are unknown or unexpected.

**5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?**

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, despite the best efforts of the researchers to avoid them. Please tell your regular doctor(s) and/or the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study.

Compensation for an injury resulting from your participation in this research is not available from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Hospital or the sponsor for the study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

## 5.3 If I take part in this study, can I also participate in other studies?

 *Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies*. You should not take part in more than one study without approval from the researchers involved in each study.

## 5.4 How could I benefit if I take part in this study? How could others benefit?

## You may not receive any personal benefits from being in this study. The researchers hope the information learned from your participation in the study will increase our knowledge about which way is best to treat patients like you who have suffered a stroke and also have high blood sugar at the hospital. This knowledge will help make it possible to provide the best type of treatment for stroke patients in the future. While you may or may not personally benefit from being in the study, your participation will provide a benefit to others with stroke and to society.

## 5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information. This information may be shared with you at the time of the 6-week phone call or the scheduled follow-up study visit.

### 6. Other options

## 6.1 If I decide not to take part in this study, what other options do I have?

You do not have to join this study or sign this Consent to Participate in Research. By not signing you would not have the opportunity to receive the study treatments. If you choose not to participate, during your hospitalization, you will receive standard care for stroke patients, which usually would include about 6 finger sticks daily and subcutaneous insulin shots to treat your blood sugar if it is high.

### 7. ENDING THE STUDY

## 7.1 If I want to stop participating in the study, what should I do?

## You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

## 7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no harm to you if you decide to leave the study before it is finished. You will still be treated for high blood sugar as part of your standard care.

## 7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

* The researcher believes that it is not in your best interest to stay in the study.
* You become ineligible to participate.
* Your condition changes and you need treatment that is not allowed while you are taking part in the study.
* You do not follow instructions from the researchers.
* The study is suspended or canceled.

### 8. Financial Information

## 8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

You will not be required to pay any extra money because of this study, but you will be responsible for the costs of the standard care for your stroke. The study will pay for the study treatment medicine that is not standard care and for the materials for the extra research finger stick blood sugar tests needed.

The normal costs of taking care of you for your stroke will have to be paid for by you or your insurance company. These costs are the same as you would be responsible for if you were not in this research study. The 3-month clinical follow up with your doctor for continuing stroke treatment and care which is not part of the scheduled research follow up activities will be not be paid for as part of the study.

## 8.2 Will I be paid or given anything for taking part in this study?

[Select from the following two statements (and delete the other) as appropriate for your local procedure:]

You will not receive payment for participating in this study.

You will receive reimbursement to compensate for transportation costs.

## 8.3 Who could profit or financially benefit from the study results?

Dr. Rattan Juneja, the study endocrinologist from the Indiana University, may profit from the commercial sales of the GlucoStabilizer. The terms of this arrangement have been reviewed and approved by Indiana University and a management plan is in place in accordance with its conflict of interest policies.

### 9. confidentiality of subject records and authorization to release your protected health information

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

## 9.1 How will the researchers protect my privacy?

## Any time information about you is collected there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Information about you collected for this research study will remain confidential, unless you give your permission to share it with others or if we are required by law to release it.

## 9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

* Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
* Mental health care records (except psychotherapy notes not kept with your medical records)
* Alcohol/substance abuse treatment records
* Your AIDS/HIV status
* All records relating to your stroke, the treatment you have received, and your response to the treatment
* Billing information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

* The researchers may need the information to make sure you can take part in the study.
* The researchers may need the information to check your test results or look for side effects.
* University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
* Study sponsors or funders, or safety monitors or committees, may need the information to:
	+ Make sure the study is done safely and properly
	+ Learn more about side effects
	+ Analyze the results of the study
* Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
* The researchers may need to use the information to create a databank of information about your condition or its treatment.
* Information about your study participation may be included in your regular medical record.
* Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The following groups may access your information as part of your participation in this study:

* Members of the SHINE Trial and the Neurological Emergency Trials Network Leadership Teams who are located at the following centers: University of Virginia, University of Texas Southwestern Medical Center, Georgia Health Sciences University, Medical University of South Carolina, University of Michigan, Indiana University, Rush University Medical Center-Chicago.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

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 the web site at any time.

## 9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

* To avoid losing study results that have already included your information
* To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
* To help University and government officials make sure that the study was conducted properly

## 9.4 When does my permission expire?

Your permission will not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you decide not to continue participating or if you withdraw consent, any information already collected about you while you were in the study will be used in this study.

The collected clinical information will be available indefinitely. This gives the investigators information to be used for medical, scientific, educational or research purposes.

### 10. Contact Information

## 10.1 Who can I contact about this study?

## Please contact the researchers listed below to:

* Obtain more information about the study
* Ask a question about the study procedures or treatments
* Talk about study-related costs to you or your health plan
* Report an illness, injury, or other problem (you may also need to tell your regular doctors)
* Leave the study before it is finished
* Express a concern about the study

Principal Investigator:
Mailing Address:
Telephone:

Study Coordinator:
Mailing Address:
Telephone:

You may also express a concern about a study by contacting the Institutional Review Board listed below.

 IRB Name:

 Mailing Address:

 Telephone:

### 11. record of Information provided

**11.1 What documents will be given to me?**

Your signature in the next section means that you have received copies of all of the following documents:

* This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular medical record.)*

**Optional SHINE Sub-Study: I-SPOT**

(Insight on Selected Procoagulation markers and Outcomes in stroke Trial)

------------------------ Use the following page only if applicable ----------------------

In addition to the main research study, there may be an optional sub-study in which you may qualify to participate. Participating in this optional sub-study is important to the research; however you may participate in SHINE without agreeing to take part in this sub-study.

The purpose of the sub-study is to gather information about the effects of high blood sugar and insulin treatment on blood clotting. The blood samples collected will be used for this purpose only.

If you decide to participate, we will collect two blood samples, one before the SHINE study treatment is started, and the second will be collected about two days later. Each blood sample will be approximately one tablespoon of blood. With blood drawing, you may experience local pain and, rarely, infection or bruising.

Your blood samples will be labeled with your SHINE study identification number and the visit date. No personal information will be on the tubes used to store the blood samples. Your blood samples will be stored at Temple University for about 3 years after the completion of the SHINE study or up to 10 years. The results of these tests will not have an effect on your care, and neither you nor your doctor will receive the results.

You are free to choose not to participate. If you do participate, you are free to withdraw at any time up until the samples are de-identified, which means the samples are not linked to you. If you have any questions, or you would like to withdraw your blood sample, you should contact the principal investigator listed in this form. If you choose not to participate or if you withdraw, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. It will not affect your ability to participate in the SHINE trial.

Please initial whether you permit the collection of a repository blood sample as described above:

\_\_\_\_\_\_ YES, I give my permission for blood samples to be collected for the sub-study I-SPOT

\_\_\_\_\_\_ NO, I do not give my permission for blood samples to be collected the sub-study I-SPOT

### 12. SIGNATURES

**Research Subject:**

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: Date: \_\_\_\_\_\_ Time:\_\_\_\_\_\_\_\_\_\_

Name (Print legal name):

Patient ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Legal Representative (if applicable):**

Signature of Person Legally

Authorized to Give Consent Date: \_\_\_\_\_\_ Time:\_\_\_\_\_\_\_\_\_\_

Name (Print legal name): \_\_\_\_\_\_\_\_\_\_\_\_ \_\_ Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address:

Check Relationship to Subject:

Parent Spouse Child Sibling Legal Guardian Other:

Reason subject is unable to sign for self:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Principal Investigator (or Designee):**

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: Title:

Signature: Date: Time:\_\_\_\_\_\_\_\_

**Witness (optional):**

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Name:

Signature: Date of Signature: Time:\_\_\_\_\_\_\_\_\_\_