Informed Consent Form- Clot Removal for Late Presenting Stroke

You are having a major stroke, which is caused by a clot blocking blood flow to a blood vessel in the brain. It has been at least 8 hours since your stroke symptoms started. Treatments to remove or dissolve blockages causing stroke are known to be effective and safe within the first few hours of a stroke. This study is designed to find out whether a procedure to remove the clot causing the stroke is helpful when it has been more than 8 hours since the stroke started.

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.** This form tells you about the study. Please ask questions about anything that is not clear.

What is the study about?

Studies have shown that it is safe and effective to use a catheter (tube in the blood vessel) to remove clots causing stroke in people who have had stroke symptoms for less than 8 hours. This study is designed to find out whether doing this procedure beyond the 8-hour limit helps to reduce disability and enhance recovery from stroke. Using this device after 8 hours from the start of stroke symptoms is considered investigational. It is not yet known whether it will help.

How is this different from what will be done normally?

Standard treatment for a patient with stroke symptoms longer than 8 hours would be close monitoring and then rehabilitation therapy. Medications are used to treat blood pressure and cholesterol, to keep the patient stable, and to reduce the risk of future strokes. This study will evaluate whether doing clot removal (in addition to standard treatment) is helpful.

This study will have two treatment groups. One group will have standard treatment and one group will have standard treatment plus clot removal.

How is it decided which group you will be in?

A computer will randomly assign you to be in one treatment group or the other. *You will have an equal (50/50) chance of being assigned to either group.*

If you are assigned to standard treatment *without* clot removal

You will receive the standard treatments that make up high quality stroke care. This includes aspirin therapy, treatment of blood pressure and cholesterol to prevent future strokes, and rehabilitation and any other treatments your doctor may recommend.

If you are assigned to standard treatment *plus* clot removal

You will be treated with standard medications and rehabilitation, just like the other group. You will also have the catheter procedure to remove the blood clot from the brain. Doctors will put a catheter into a blood vessel in your groin. IV dye will be used to take pictures of

the blood vessels. A clot removal tool will then be used to remove the clot. *If the tool doesn't remove the clot completely, you may be treated with other treatments as determined by your doctor.*

What will be required of you?

Regardless of which group you are in, you will have 4 follow-up checks over the next 3 months. Details of these visits are included in the accompanying study information sheet.

What are the possible benefits of being in the study?

You may or may not directly benefit from being in this study. It is possible that removing the clot may stop your stroke from progressing and reduce your disability or impairment from stroke. The knowledge gained from this study may help doctors learn more about what treatments are effective for stroke.

What are the possible risks of being in the study?

If you are assigned to the standard treatment group, there are no added treatment-related risks. If you are assigned to the clot removal procedure, the most common complication is bleeding or bruising in the groin where the puncture was made. Possible major risks from clot removal procedures include bleeding in the brain, worsened or new stroke, tearing or injuring blood vessels, allergic reaction from dye, and death. These are not common but can happen. 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 this study is to be treated with standard, high-quality treatment.

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

If you get ill or injured from being in the study, XXXX will help you 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 XXX 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 to your insurance for being in this study. Payment for your stroke treatment will be handled just as it would be if you were not in the study, according to the terms of your insurance policy.

Will you be paid for being in the study?

You will not receive payment for being in this study.

Will your information be kept private?

XXXXX will keep your information private in accordance with research regulations. We will use a code rather than your name to label your information, and we will not identify you in research reports. However, your records may be reviewed by study sponsors or the federal Food and Drug Administration, 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.

We want to answer questions you may have about the study now or at any time. If you decide to participate, your doctor or someone from the study team will talk with you again after your procedure and answer any questions you may have about the study.

Whom can you contact if you have questions or concerns?

The doctor, nurse, study team etc. XXXX

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

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