

## **Consent for Treatment of Acute Ischemic Stroke with tissue Plasminogen Activator**

### **What is a stroke?**

A stroke is a problem with the tubes or vessels bringing blood to the brain, such that a part of the brain is injured. There are two main types of stroke, those associated with rupture of the blood vessels (hemorrhagic strokes) and those associated with the blockage of blood vessels (ischemic strokes).

### **What happens in an acute ischemic stroke?**

In an acute ischemic stroke, the blood flow to a part of the brain is interrupted because of sudden blockage of a blood vessel. The blockage is usually due to a blood clot and starves the brain of needed oxygen and nutrients. The center of the starved area may die quickly, and the surrounding area may die slowly over hours.

### **What is tissue plasminogen activator or tPA?**

TPA is a medication that can dissolve blood clots. Because of its strong blood thinning action, bleeding into or around the brain can result as a side effect of its use. (6% risk). Bleeding can also occur in other parts of the body. (Approximately 5% risk)

### **How can tPA help someone with an acute ischemic stroke?**

tPA can sometimes dissolve the clot that is blocking the blood vessel and causing the ischemic stroke. If it does so, the blocked blood vessel reopens, allowing the previously starved brain to receive blood flow again with oxygen and nutrients. If the clot is dissolved soon enough, some or all of the brain may be rescued from the threatened injury. Rescuing brain that was starved may decrease the amount of disability that results from the ischemic stroke.

A recent research study demonstrated that, overall, patients given tPA within 3 hours of ischemic stroke onset had better outcomes 3 months later than patients not given any treatment.

### **Do all stroke patients get this treatment?**

No. Specific criteria are used to identify those patients most likely to benefit and to avoid serious side effects. If a stroke patient does not fulfill all of those criteria, the risks of therapy are probably higher and the chance of benefiting probably lowers.

### **What are the potential benefits?**

The potential benefits are all related to an increased chance of having a good outcome, namely little or no disability remaining after recovery from the stroke. If stroke patients meet all the criteria, their chance of having a good outcome increases from 29% without tPA to 41% with tPA. Thus, even though the chances of a good outcome are improved, over half of the stroke patients who are given tPA will still have disability from their stroke. A good outcome is not guaranteed.

**What are the potential risks?**

The major risk of tPA therapy in stroke patients is that they will bleed into the injured area of the brain, causing a worsening of their condition and even death. The chance of serious bleeding into the stroke area is less than 0.6% in stroke patients not treated with tPA versus 6.4% in those who get tPA. In other words, tPA increases about 10 times the chance of a bleed that can worsen a patient’s condition. Overall, mortality rates are unchanged. About 20% of patients will die within 30 days of their strokes, regardless of tPA.

**What tests will be done?**

No testing beyond what would be routine in a patient with stroke will need to be done. These standard tests include blood work and imaging, including a CT scan of the head to make sure no hemorrhage nor early severe signs are present before proceeding the tPA therapy. A repeat CT scan and further blood testing may be performed depending on how the patient responds to treatment.

I understand that the results of tPA treatment for stroke cannot be guaranteed. I have read and understand the above. My physician has offered to answer all inquiries concerning the proposed treatment with tPA. I understand that I am free to withhold or withdraw consent to the proposed treatment with tPA at any time.

Witness:	Signature of person giving consent:
Date and Time signed:	Relationship to patient (if applicable):