

**AUTHORIZATION AND CONSENT FOR INTRAVENOUS THROMBOLYTIC TREATMENT OF NON-BLEEDING STROKE**

I/we, \_\_\_\_\_, authorize and consent to intravenous thrombolytic treatment for \_\_\_\_\_ (patient's name) for non-bleeding stroke under the supervision of the emergency department physician.<sup>1</sup>

I am the \_\_\_\_\_ spouse, \_\_\_\_\_ child, \_\_\_\_\_ guardian or conservator of the patient. I agree with the emergency department physician that the condition of the patient may not allow for adequate interaction to obtain informed consent.

I understand that the patient must undergo a CT scan. Once the CT scan has been completed, it will be interpreted by a physician who specializes in radiology and the radiologist's interpretation of the CT scan will be transmitted to the emergency department physician.<sup>2</sup> Whether intravenous thrombolytic treatment will be an option depends, in part, upon the radiologist's interpretation of the CT scan. The protocol in use at St. Someone's Hospital for intravenous thrombolytic treatment has been developed in consultation with specialists in the field of neurology.

**Duration of symptoms before arrival:** You have advised the emergency room nursing staff and the emergency room physician that the first symptoms of the patient's stroke occurred no earlier than \_\_\_\_\_ hours on \_\_\_\_\_. This representation is extremely important. Presently available information indicates that the risks associated with intravenous thrombolytic treatment of acute stroke exceed the hoped-for benefits. If three (3) or more hours have passed from the time symptoms began until intravenous stroke therapy has actually started, the physicians and other health care providers involved in the care of the patient are proceeding with treatment based upon your representation regarding the time the symptoms began. Unless you verify this history with your signature, treatment cannot proceed further.

\_\_\_\_\_  
Responsible person signature

\_\_\_\_\_  
Date/time signed

\_\_\_\_\_  
Responsible person signature

**Description of the procedure:** A clot-busting drug called Activase™ (t-PA) is infused through the patient's vein. This medication is given in an effort to restore blood flow and oxygen to the part of the brain that the stroke is damaging. The medication will be given over a period of approximately 1 hour. During this time and afterwards, the patient will be monitored by physician and nursing staff. After the medication is started, the patient will be moved to the intensive care unit (ICU) for additional care and monitoring.

**Potential benefits:** If the clot-busting drug succeeds in restoring blood flow and oxygen to the part of the brain having a stroke, there may, or may not, be improvement. Often a period of time must pass before any benefit from the clot-buster is apparent. Sometimes this can be up to 90 days. The NINDS studies conducted with this medication demonstrated that 30% of

patients receiving clot-busting therapy within 3 hours of the onset of stroke have been restored to normal or near normal by 90 days.

**Risks of the procedure:** Intravenous thrombolytic treatment for probable stroke was approved by the FDA in 1996 and is not experimental. FDA approval does not guarantee safety or success. Every medical procedure or treatment carries risks of varying significance.

Intravenous thrombolytic therapy of probable stroke includes serious risks not limited to death, small or widespread bleeding in the brain and in the skull causing temporary or lifelong loss of the ability to see, walk, talk and function, loss of bowel and bladder control, gastric bleeding, hemorrhage from sites of old clots which may have been unknown, bleeding from intravenous sites and infection, nerve damage, and inflammation of the skin at the site of the intravenous line(s).

The most significant risk of clot-busting medication is bleeding. When bleeding occurs in the brain, as it did in 6% of patients who received this medication in the "NINDS" stroke trial, the usual outcome is death. Surgical drainage of such bleeding may not be possible or, if performed, may not produce any benefit. Bleeding in other areas of the body may also be life-threatening and require surgical and/or medical treatment. It may not be possible to distinguish between complications of the treatment and complication of the stroke itself. A transfusion with the risks of diseases including HIV or AIDS may be required. Urgent transfer to another facility may be necessary for specialized testing and interventions, including cerebral arteriography and neurosurgery. You are considering authorization of critical care medicine, in a compressed time frame, in a community hospital. Human error may occur in these urgent circumstances.

**Treatment is optional:** Even if intravenous thrombolytic treatment is an option for you or your family member, it is your choice whether or not to proceed. Treatment is not mandatory. The patient will not be abruptly discharged from the hospital due to a decision not to proceed with intravenous thrombolytic treatment.

**Significant alternatives:** At present, there is one (1) other FDA-approved option (MERC1) that can be used for up to 8 hours from the onset of symptoms. If this option is chosen, a transfer to another facility will be required.

**CERTIFICATION**

I have reviewed the information contained in this authorization and consent. I have had the opportunity to address all of my questions with the emergency department physician. I authorize and give my/our informed consent to proceed with intravenous thrombolytic treatment.

\_\_\_\_\_  
Patient, as printed by responsible person

\_\_\_\_\_  
Signature, responsible person

\_\_\_\_\_  
Date                      Time                      Relationship to patient

\_\_\_\_\_  
Date                      Time                      Witness signature

<sup>1</sup> The emergency department physician is not the employee of St. Someone's Hospital.

<sup>2</sup> The radiologist is not the employee of St. Someone's Hospital.