Date

RE: Your feedback about a new research study for patients qualifying for the Recombinant Factor VIIa for Acute hemorrhagic Stroke Administered at Earliest Time (FASTEST) Trial

Dear Community Member,

We would like your feedback about a research study that may be conducted in <city/location>. Physicians at <site name> Hospital plan to participate in a national multi-center study funded by the National Institutes of Health (NIH) about the emergency care for patients with bleeding in the brain also called intracerebral hemorrhage or ICH. The study is called FASTEST.

FASTEST is a study involving patients who have had bleeding in the brain also called intracerebral hemorrhage or ICH. ICH occurs because a weakened blood vessel in the brain breaks and the bleeding accumulates in the brain. Most of this bleeding occurs within a few hours of onset of symptoms. The brain injury from ICH is usually very severe and over 40% of people with ICH are dead within a month and only 20% can independently care for themselves at 6 months. There is currently no treatment for intracerebral hemorrhage that is scientifically proven to improve outcome.

Because of the severity of the brain injury, patients with ICH are usually very poorly responsive and cannot tell physicians whether or not they would want to participate in a study.

The FASTEST study is being done to determine if Recombinant Factor VIIa (rFVIIa), a protein that our body makes to stop bleeding at a site of injury to a blood vessel, can slow bleeding in the brain and improve outcome. rFVIIa is approved for treatment of bleeding in patients who have inherited lack of clotting factors but is not approved for treatment of ICH. In previous research studies in people that had a stroke caused by ICH, treatment with rFVIIa showed different results. In one study it slowed bleeding in the brain compared to placebo and improved outcome at 90 days after the stroke. In another larger study that included more participants, it slowed bleeding but it did not improve outcome. Participants chosen for the current FASTEST study represent the subgroup of patients with ICH from the previous studies who may be most likely to benefit. For example, it appeared that participants treated sooner after their stroke did better and this is why the treatment in the FASTEST study must be given within 2 hours of onset of symptoms. In all of these studies, serious side effects, such as heart attacks or strokes due to blockages of blood vessels, occurred slightly more often in participants that received recombinant FVIIa.

The study will involve patients brought to a participating hospital Emergency Department or evaluated in a mobile stroke unit who meet the following general enrollment criteria:

- **Bleeding in the brain as determined by imaging of the brain**
- **Ages 18 to 80 years, inclusive**
- **ICH volume of 2 to 60 cc (very big and very small brain hemorrhages are excluded)**
- **Intraventricular hemorrhage score of 7 or less (big hemorrhages in the brain's fluid sacs called ventricles are excluded)**
- **Glasgow Coma Scale of 8 or more (patients in deep coma are excluded)**
- **Treatment initiated within 2 hours of symptom onset**

Participants in the FASTEST study are put at random, that is by chance, in one of 2 groups. One group receives rFVIIa intravenously over 2 minutes within two hours of onset of symptoms and the other group receives placebo (no active ingredient). We do not know if rFVIIa is better than placebo. The results of the FASTEST study will help doctors discover if rFVIIa improves outcome in patients with bleeding in the brain. Medical care otherwise will be identical for the two treatment groups including close management of blood pressure and care within an intensive care unit. The study team will follow participants for 180 days after enrollment to evaluate their outcome.

Patients usually must consent to be in a medical study. The patients in this study will be unable to consent for themselves. When possible, consent to participate in the study is sought from the family member or legal representative of a patient with ICH before including the patient in a study. However, since the study medication must be given within 2 hours of onset of symptoms, there might not be enough time to locate and talk to the person's family member or legal representative about the study. If a family member or representative of the patient is not available to decide for the patient, a patient may be enrolled in this study without consent. This is called Exception from Informed Consent (EFIC) for emergency research. Once the family member or legal representative is located, they will be asked to give their permission for the patient with bleeding in the brain to continue in the study. Because of this, we are asking community members to think about this research and let us know what you think about the study.

The U.S. federal government has created a set of special rules for exception from informed consent for emergency research.

EFIC can only be used when:

- The person's life is at risk, AND,
- The best treatment is not known, AND
- The study might help the person, AND
- It is not possible to get permission:
    - from the person because of his or her medical condition nor
    - from the person's guardian because there is a very short amount of time required to treat the medical problem

Before researchers may do a study using EFIC, they must provide information about the study to the community and get their feedback. That is why we are writing to you today.

A survey is enclosed and can be returned using the enclosed self-addressed stamped envelope or using the survey link.

By completing this survey, you will be taking part in an important discussion about the study called "community consultation." Your feedback is important to us. Having now read about the study, please complete the survey and tell us what you think about the study.

If you would not want to be included in the study in the unlikely and unfortunate circumstance that **you** suffer a stroke due to bleeding in the brain, you can let us know that as well. If you would not want to be enrolled, you can use the links to get an Opt-out card to print, call or send us an e-mail with your contact information, and the study team will provide you with an Opt-out card that says "FASTEST Research Study Declined." This card communicates your wishes to emergency doctors, nurses, and researchers when you cannot and should be

carried during the 3 ½ years we expect he study to enroll. If you suffer bleeding in the brain and do not take part in the study, you will receive the standard medical care for bleeding in the brain.

If you would like to read more about this study, please visit the national website at https://nihstrokenet.org/fastest/home, or contact our local study team at xxx-xxx-xxxx.

Sincerely,

<Study PI Name>
<Title>
<Address>