Researchers at more than 100 other hospitals across the United States and other countries are joining to conduct a research study of bleeding in the brain called FASTEST. This study may affect you or someone you know and we need to find out ahead of time what the residents of the U.S. and local communities think about it. THANK YOU for your help and time in completing this survey.

There are no known risks involved in participating in this survey. Your participation in this survey is completely voluntary. You may refuse to participate and not answer any questions that you do not feel comfortable answering.

FASTEST is a research 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 ICH 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 research 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 (no active ingredient) 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 research 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 rFVIIa.

1. Have you or someone you know ever experienced bleeding in the brain or ICH? (check all that apply)

☐ No ☐ I have ☐ My child has ☐ A family member or loved one has ☐ Someone else I know has

Participants in the FASTEST study are put at random, that is by chance, in one of 2 groups. They have an equal chance of getting rFVIIa or placebo (no active ingredient). One group receives rFVIIa intravenously over 2 minutes within two hours of onset of symptoms and the other group receives placebo. We do not know if rFVIIa is better than placebo for patients with bleeding in the brain. 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 the 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 ICH 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 asking you to complete this survey today.

Please **DO NOT** write your name on this form

Please tell us how much you agree with each of the following FASTEST study statements below.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. FASTEST is an important study to do.	◯	◯	◯	◯	◯
2. If I had bleeding in the brain, I would be okay with being included in FASTEST without giving your consent ahead of time.	◯	◯	◯	◯	◯
3. If my spouse or family member had bleeding in the brain, I would be okay with him/her being included in FASTEST without giving my consent ahead of time.	◯	◯	◯	◯	◯
4. I am in favor of this study being conducted in my community?	◯	◯	◯	◯	◯

5. Do you think that FASTEST researchers will seriously consider what community members like you have to say about this study before starting it?

◯ Yes ◯ No ◯ I don't know

6. Do you feel that you have been given enough information to give your informed opinion about whether you think it is okay for researchers to do the FASTEST study?

◯ Yes ◯ No (What additional information would you still like to know?)

_____

_____

_____

We would like to hear your thoughts in your own words.

7. Do you have any positive thoughts or comments that you wish to share about the FASTEST study and the study being in your community?

_____

_____

_____

8. Do you have any negative thoughts or concerns that you wish to share about the FASTEST study and the study being in your community?

_____

_____

_____

9. IF you do not want to participate in FASTEST or to learn more about the study please see information below.

To Opt-out and not be enrolled in the FASTEST STUDY, if you should experience a brain hemorrhage, please pick up a FASTEST opt out card, print an opt out card one from the FASTEST Stroke Net Website or contact the study team listed to learn how you obtain an Opt-Out card. Once you have an Opt-Out card carry it all times and let your family know your wishes.

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Local Site Study Contacts

Primary Investigator: <Provide>
Contact Person: <Provide>
Contact Phone Number: <Provide>

Website: https://nihstrokenet.org/fastest/home

Lastly, so that we can make sure we are hearing from a wide range of community residents, please complete the following final few questions about yourself. This information is only used to demonstrate community participation and is not retained for research.

10. What is your *age:* _____(years old)

11. Are you: ◯Male ◯Female ◯ Others

12. Are you Hispanic or Latino? ◯ Yes ◯ No ◯ I don't know

13. Which one or more of the following would you say is your race: (Check all that apply)

◯ White (including Middle Eastern)

◯ Black or African American

◯ Asian

◯ Native Hawaiian or Other Pacific Islander

◯ American Indian or Alaska Native

◯ Other [specify]_____

14. What is your primary language?

◯ English

◯ Spanish

◯ Arabic

◯ Cantonese

◯ Other, please specify: _____

15. What is the highest grade or year of school you completed?

◯ Never attended school or only attended kindergarten

◯ Grades 1 through 8 (Elementary)

◯ Grades 9 through 11 (Some high school)

◯ Grade 12 or GED (High school graduate)

◯ College 1 year to 3 years (Some college or technical school)

◯ College 4 years or more (College graduate)

16. What is your zip code? (Information is only used to demonstrate community participation and is not retained for research)

Zip code: _____

17. How did you hear about this survey?

◯ In an email or online from a group or organization you are a member of

◯ Other: _____

If you received this survey in an email or online, please list the name of the group or organization and the social media account, if applicable.

_____

Thank you for your assistance.

Which FASTEST Study Site are you near? Please mark all that apply

- University of Alabama Hospital, Birmingham, AL
- St. Joseph's Hospital and Medical Center, Phoenix, AZ
- Cedars-Sinai Medical Center, Los Angeles, CA
- Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA
- Mercy San Juan Medical Center, Carmichael, CA
- Mills-Peninsula Medical Center, Burlingame, CA
- Ronald Reagan UCLA Medical Center, Los Angeles, CA
- San Francisco General Hospital, San Francisco, CA
- UC Irvine Medical Center, Orange, CA
- UCSD Health La Jolla, La Jolla, CA
- UCSD Medical Center - Hillcrest Hospital, San Diego, CA
- UCSF Medical Center, San Francisco, CA
- University of Colorado Hospital, Aurora, CO
- Grady Memorial Hospital, Atlanta, GA
- The Queen's Medical Center, Honolulu, HI
- Central DuPage Hospital, Winfield, IL
- Loyola University Medical Center, Maywood, IL
- University of Chicago Medical Center, Chicago, IL
- Baystate Medical Center, Springfield, MA
- Lahey Hospital & Medical Center, Burlington, MA
- Massachusetts General Hospital, Boston, MA
- UMASS Memorial Medical Center, Worcester, MA
- Fairview Southdale Hospital, Edina, MN
- Mayo Clinic Saint Mary's Campus, Rochester, MN
- Regions Hospital, St. Paul, MN
- Barnes Jewish Hospital, St. Louis, MO
- St. Josephs Regional Medical Center, Paterson, NJ
- Mount Sinai West, New York, NY
- NYP Columbia University Medical Center, New York, NY
- North Shore University Hospital, Manhasset, NY
- Stony Brook University Hospital, Stony Brook, NY
- Wake Forest Baptist Medical Center, Winston-Salem, NC
- Cleveland Clinic Akron General (Akron OH)
- Cleveland Clinic, Cleveland, OH
- Riverside Methodist Hospital, Columbus, OH
- OSU Wexner Medical Center, Columbus, OH
- Toledo Hospital (ProMedica), Toledo, OH
- University of Cincinnati Medical Center, Cincinnati, OH
- Providence St. Vincent Medical Center, Portland, OR
- Abington Memorial Hospital, Abington, PA
- Thomas Jefferson University, Philadelphia, PA
- Greenville Hospital System, Greenville, SC
- Medical University of South Carolina University Hospital, Charleston, SC
- Methodist University Hospital, Memphis, TN
- Memorial Hermann Texas Medical Center, Houston, TX
- University of Utah Healthcare, Salt Lake City, UT
- VCU Medical Center, Richmond, VA

Thank you!

Local Site Study Contacts

Primary Investigator: <Provide>
Contact Person: <Provide>
Contact Phone Number: <Provide>

Website: https://nihstrokenet.org/fastest/home