BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK
KINGS COUNTY HOSPITAL CENTER

SUBJECT INFORMATION AND INFORMED CONSENT FORM

Protocol Title:	Rapidly Improving Stroke Symptoms (RISS): A Pilot Study
Protocol #:	H2
Sponsor:	Investigator Initiated
Principal Investigator:	Lorenzo Paladino, MD
Institution:	Kings County Hospital Center
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We are asking if you want to be in a research study. This study is for people who have had a STROKE ("Brain Attack").

WHAT YOU SHOULD KNOW ABOUT RESEARCH STUDIES:

- This consent form gives you information about the study. It tells you about the purposes, risks, and benefits of this research study.
- There may be risk to participating in this study.
- Your participation is voluntary. You do not have to be in this research study. You can agree to be in the study now and change your mind later.
- Your decision will not affect your regular care. Your doctor's attitude toward you will not change.
- Please read this consent form carefully.
- Ask any questions you have before you make a decision. The study doctor will answer your questions.
- You may consult with your family or friends.

WHY IS THIS RESEARCH BEING DONE?

We are doing this study to find out how stroke symptoms change within the first few hours after a stroke. Some people get better, and some people get worse. When people get better, doctors sometimes do not treat them with medicine that breaks down blood clots. We want to see if these people do better or worse than people who get the medicine. About 50 people will be in the study.

WILL IT COST ME MONEY TO BE IN THIS STUDY?

Your insurance provider will be billed for the clinic visits and for the usual tests (standard of care) given to you to monitor your medical condition and/or to determine whether or how much the therapy is helping you. Therefore, we will bill your insurance provider and you will be billed for any costs that the insurance provider decides should be passed on to you, such as copayments or deductibles. You will not have to pay any money if you agree to be in this study.

You will not be paid to participate in this study.

WHAT WILL HAPPEN TO YOU IF YOU DECIDE TO BE IN THIS STUDY?
This part of the study will take place while you are in the Emergency Room and while you are admitted to the hospital:

- Someone from the study team will go over the consent form and if you agree to participate, we will ask you or your legally authorized representative to sign the consent form.
- A doctor will examine you to see how bad your stroke is using an exam called a Stroke Scale. This is part of the usual treatment for stroke
- You will get a CT scan, which is a series of pictures (like an x-ray) of the brain. This is part of the usual treatment for stroke.
- A member of the stroke study team will examine you using the Stroke Scale about every 20-30 minutes. They will do this until your doctor decides if you will be treated with medicine that breaks down blood clots.
- Your doctor will decide what treatment you will get for your stroke. The stroke study team will examine you using the Stroke Scale at 2 hours and 24 hours after this treatment decision.
- Either you will get a final Stroke Scale exam on the day you are discharged from the hospital, or on the 7th day you are in the hospital, whichever comes first. In addition to the Stroke Scale, a member of the stroke study team will examine you to see how much your stroke has affected you. They will use a scale that measures disability (mRS).

This part of the study will take place 3 months after your stroke either in the Outpatient Clinic at the hospital or over the phone:

- A member of the stroke study team will examine you in person using the Stroke Scale and the mRS scale.

OR

- A member of the stroke study team will call you on the phone and ask you questions about any problems you have had after your stroke.

The only additional procedures that you will do as part of this study will be the multiple examinations with the Stroke Scale and the final disability scale (mRS).

WHAT ARE THE POSSIBLE RISKS OF BEING IN THE STUDY?
You may feel tired or frustrated from being examined with the Stroke Scale so many times. We will try to make sure that you get enough rest in between the scales.

WHAT ARE THE POSSIBLE BENEFITS OF BEING IN THE STUDY?
There is no direct benefit to you for participating in the study. Information from this study could help future stroke patients by determining which patients do well and do not do well with the stroke.

ALTERNATIVES
The alternative in this study is not to participate. You will receive the same treatment for your stroke whether or not you decide to be in the study.

IF YOU HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN YOU CALL?
If you have any questions relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, you may contact Dr. Paladino at 718-245-2973.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

CONFIDENTIALITY
To the extent allowed by law, every effort will be made to keep your personal information confidential. Medical records, which identify you and the consent form signed by you, will be looked at by study representatives and may be looked at by regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION
Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- Department of Health and Human Services agencies
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- HHC Corporate Research Staff Members
- Accrediting agencies
- Health Insurers/Payors

Your personal health information may be further shared by the groups above. If shared by them, the

information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health confidential.

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled.

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Notice Concerning HIV-Related Information: The recipients of HIV-related information are prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at 212-480-2493 or the New York City Commission on Human Rights at 212-306-7450. These agencies are responsible for protecting your rights.

CAN YOUR BEING IN THE STUDY END EARLY?

Being in this study is voluntary. You do not have to be in the study if you do not want to. You can agree to be in the study now and change your mind later. If you want to quit the study, you should talk to Dr. Paladino or one of the study staff members.

The researchers can take you out of the study without your permission. Possible reasons for this are:

- Being in the study would be unsafe for you
- You do not follow the instructions given to you by the study staff

If your being in the study ends early, we may ask you to visit the study doctor for a final visit to examine you for any change in your stroke severity.

New York City Health and Hospitals Corporation can also suspend or cancel this research.

WHAT ELSE DO YOU NEED TO KNOW?
If we find out any new information that might affect your decision to stay in the study, we will give it to you.

WHAT IF YOU ARE INJURED?
You might be injured by being in this study. If you are, emergency care will be available. New York City Health and Hospitals Corporation does not provide financial compensation for injury or illness from participation in research. Payment for medical treatment, both standard and experimental, as well as treatment of any side effects will be assumed in the usual manner by you personally or through your medical insurance. However, medical care for any injury or illness resulting from patient participation is available regardless of ability to pay.

No other compensation will be offered by Kings County Hospital Center, New York City Health and Hospitals Corporation, or BRANY. By signing this form, you are not waiving any legal right to seek additional compensation through the courts.

SUBJECT CONSENT
By signing this consent form, you accept that you read this form, or had it read to you. You agree to be in the study and authorize the use and reporting of your individual identifiable health information (IIHI) as explained in this form. You will not be giving up any of your legal rights by signing this consent.

Signature of Subject (or Legal Guardian)	Date	Print name

Signature of Person Obtaining Consent	Date	Print name