CONSENT FORM

State University of New York, SUNY, Downstate Medical Center and Kings County Hospital Center, Brooklyn, New York

Study Title

The **R**apid vascular **U**ltrasound evaluation and serial **N**eurological assessment in minor stroke and rapidly improving symptoms, **RUN**, study.

We are asking if you want to be in a research study. This study is for people who have had a stroke or a transient bran ischemic attack (TIA).

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.
- ***Regular care*** is based on the best-known treatment. The main goal of regular care is to help the individual patient. The main goal of ***research studies*** is to learn more so that we can help future patients. You might benefit from being in the study, but we cannot promise this.
- There may be risk to participating in this study.
- Your participation is voluntary. You don't 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.

1) Why is this research being done?

People who have a stroke or a TIA may immediately get better or worse. We are doing this study to find out how and why stroke symptoms change within the first 12 hours after a stroke. When people get better immediately after a stroke or a TIA the blood clot causing the symptoms may have already broken up or remain to cause another brain ischemic attack.

We are planning to do an ultrasound test of the arteries in the brain to see if the blood clot causing the stroke is still there. An ultrasound is a non-invasive and non dangerous way to look inside the arteries.

2) Who is doing the study?

Dr. Steven R. Levine and Dr. Clotilde Balucani are in charge of this study at this location. About 122 people will be in the study at this location.

Dr. Clotilde Balucani is funded by the American Heart Association to conduct this study.

3) *Will it cost me money to be in this study?*

You will not be required to pay any extra money because of this study, but you will be responsible for the costs of the standard care for your stroke.

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.

4) You cannot be in this study if:

1) You are younger than 18 years old;
2) Your stroke symptoms started more than 12 hours ago; 3) You are currently pregnant or currently breast feeding.

5) Pregnancy:

You cannot participate in this study if you are currently pregnant or currently breast feeding.

6) What will happen to you if you decide to be in this study?

The following procedures will take place while you are in the Emergency Department or while you are admitted to the hospital:

- Someone from the study team will go over the consent form with you and if you agree to participate we will ask you or your legally authorized representative to sign

the consent form.

- If you are admitted within 4.5 hours from symptoms onset, and you are still eligible to receive a blood thinner medicine, a member of the stroke study team will examine you using the Stroke Scale about every 20-30 minutes until the doctor in charge decides if you will be treated with the blood-thinner medicine that breaks down blood clots or not. After a decision about your treatment is made by the doctor in charge, the stroke study team will examine you using the Stroke Scale at:
  - around 6 to 7 hours from symptoms onset;
  - 12 hours;
  - 24 hours from symptoms onset.

- If you are admitted between 4.5 to 12 hours from symptoms onset, and you are not anymore eligible for receiving the blood thinner medicine, a member of the stroke study team will examine using the Stroke Scale at the time of enrollment and then at 24 hours from symptom onset.

- In both cases, a member of the stroke study team will examine your arteries at the neck and in the brain using two non-invasive tests, which arecalled "Carotid Duplex and Transcranial Doppler". These tests use "ultrasound energy" to see if there is a clot in the arteries. These exams will last for about 15 minutes.

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 (called "Rankin Scale").

The following procedures 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 Rankin 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.

7) What are the possible risks of being in the study?

If significant new findings regarding a potential harmful effect in using ultrasound as diagnostic tool develop during the course of the study that might affect your willingness to participate, this information will be reported to you as soon as possible. You may have a risk or side-effect we don't know about yet.

You might develop a new condition or suffer an injury. If you do, you should tell the

study doctor immediately.

Additionally, 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.

8) What are the possible benefits of being in the study?

There is no benefit to you for participating in the study. The researchers hope the information learned from your participation in the study will increase our knowledge about which way is best to treat patients like you who have suffered a stroke. This knowledge will help make it possible to provide the best type of treatment for stroke patients in the future. While you may or may not personally benefit from being in the study, your participation will provide a benefit to others with stroke and to society.

9) What are your other choices?

The alternative to being in this study is to not participate.

10) If you have any questions or problems, whom can you call?

If you have any questions about this study, you can call Dr. Steven R. Levine at (718) 270-3188 or Dr. Clotilde Balucani at (718) 221-5749.

If you think you have been injured because of the research, you should call Dr. Levine at (718) 270-3188 or Dr. Clotilde Balucani at (718) 221-5749 Principal and Co-Principal investigators respectively for this study at the SUNY HSCB University Hospital or Dr. Richard Sinert at (718) 245-2973 Principal Investigator of this study at the Kings County Hospital Center.

If you have questions about your rights as a research subject, you can call the IRB office at (718) 613-8480, or you can contact the SUNY HSCB University Hospital Medical Director's Office at (718) 270-2401 or the Kings County Hospital Center Medical Director's Office at (718) 245-3921.

Call (718) 270-2121 24 hours a day and ask for a Neurology Attending for study-related emergencies.

11) What information do we keep private?

In this study we will keep your personal information confidential. We will hold your identity confidential and all data will be kept in a secure, limited access location. We will not reveal your identity in any publication or presentation of the results of the study. However, confidentiality cannot be guaranteed; your personal information may be disclosed if so required by the Federal Privacy law.

Case report forms, CD/DVD containing your brain imaging and ultrasound tests will be collected, de-identified, coded according to a serial study number and locked in a secure place - in Dr. Steven R. Levine' office (room B6-344) - with access restricted to the study personnel.

Federal law protects your right to privacy concerning Individually Identifiable Health Information (IIHI). There are certain things you need to know, IIHI is any information from your medical record, or obtained from this study, that can be linked to you, and that refers to your mental or health conditions in the past, the present or the future.

For this study we will create, use or report the following IIHI:

- Information from your medical records including your past medical history, previous hospitalizations and previous results from cerebrovascular ultrasound tests and/or neuroimaging exams.
- Information obtained from this study, including your responses to Stroke Scale and mRS examination and your Carotid and Transcranial Ultrasound exams results, neuroimaging exams like MRI and/or CT, physical examinations, laboratory tests, X-rays, Carotid and Transcranial Ultrasound exams, or any other treatment and follow-up results.

The researchers - Dr. Steven R. Levine, Dr. Clotilde Balucani, Dr. Richard Sinert, Dr. Ninfa Mehta, Dr. Lorenzo Paladino, Dr. Helen Valsamis, Dr. Diana Rojas-Soto, Dr. Volodymyr Vulkanov, Ms. Saroj Kunnakkat, Ms Sarah Zelonis - their staff and the staff of SUNY Downstate Medical Center and the staff of KCHC participating in the research will use your protected IIHI for this research study.

Your IIHI will be shared with the following persons or agencies for purposes related to the conduct of the research:

- The Institutional Review Board of SUNY Downstate Medical Center;
- The KCHC and University Hospital of Brooklyn officials;
- The Federal Office for Human Research Protections;
- The RUN Study External Advisory Committee (EAC): composed of Dr. Andrei V. Alexandrov from the University of Alabama at Birmingham, UAB, Birmingham, Alabama) and Dr. E. Feldmann from the TUFTS Medical Center, Boston, MA.

We will have to use and report your health information for an indefinite period of time.

Some IIHI that is obtained in this study will not be shared with you. This includes ultrasound tests (both Carotid Duplex ultrasound and Transcranial Doppler) results. This information can be shared with you at the end of the study.

You can withdraw this authorization for the use or reporting of your IIHI. You have to write to us to withdraw at the following address: Dr. Steven R. Levine, and Dr. Clotilde Balucani The State University of New York (SUNY) – Health Science Center Brooklyn, Department of Neurology, 450 Clarkson Avenue, Box 1213, Brooklyn, NY 11203-2098.

If you withdraw we will stop collecting and accessing your IIHI, but we will collect and report any adverse event (bad effect) that you had in the study. Your IIHI collected before you withdraw your authorization will still be used and reported.
If you withdraw your authorization you can no longer be in the study.

12) 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 don't 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. Steven R. Levine or Dr. Clotilde Balucani or one of the study staff members.

Dr. Steven R. Levine and/or Dr. Clotilde Balucani can take you out of the study without your permission. Possible reasons for this are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ The study is suspended or canceled.

13) 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.

You might be injured by being in this study. If you are, emergency care will be available. SUNY Downstate Medical Center does not have a policy to pay if you are injured by being in the study.

If your study visit(s) take place at Kings County Hospital Center, 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; unless a Sponsor, such as a pharmaceutical or device manufacturer agrees to compensate you for treatment costs for a research related injury not covered by your insurance. However, medical care for any injury or illness resulting from patient participation is available regardless of ability to pay.

14) 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. We will give you a copy of this form and of DMC's and KCHC's Notice of Privacy Practice.

Signature of Subject or Legally Authorized Representative (LAR)	Date	Print name
Relationship to subject if LAR		
Signature of Person Obtaining Consent	Date	Print Name
Signature of Witness (if applicable)	Date	Print name