CONSENT FORM

SUNY Downstate Medical Center
UHB at Long Island College Hospital
Brooklyn, NY

Antihypertensive Treatment of Acute Cerebral Hemorrhage (ATACH)-II: A Phase-III randomized multi-center clinical trial of blood pressure reduction for hypertension in Acute Intracerebral Hemorrhage

We are asking if you want to be in a research study. This study is for people who have had a stroke where there is bleeding in the brain.

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 discuss this with your family or friends.

1) Why is this research being done?

The purpose of this study is to find out if reducing your blood pressure to a lower level than the usual treatment is better for subjects who have bleeding in the brain. This is the most serious and deadly type of stroke. Doctors try to reduce a persons blood pressure when they have a stroke where there is bleeding in the brain. This is because it may lower the chance of more bleeding. We think that reducing blood pressure to a lower level will be better for study participants because of a previous study. In that study, subjects with

bleeding in the brain who had their blood pressure reduced to a lower level did better than subjects who only had their blood pressure lowered to the standard level. The standard level means your blood pressure is less than 180 mmHg. The lower level means your blood pressure is less than 140 mmHg. A branch of the government called The Food and Drug Administration (FDA) have approved this study medicine. The medicine is called nicardipine hydrochloride (Cardene®) and it is used to lower blood pressure. Doctors usually use nicardipine to treat people who have had a stroke where there is bleeding in the brain because it reduces high blood pressure. Intravenous (IV) nicardipine is a drug given through a needle in a vein. It is used for a short period of time. Doctors use IV nicardipine when they do not want to use pills. The way we are going to see which blood pressure target is better is to follow the study participants in this study for 3 months and see how they do. We will also examine your brain imaging tests to see if there is a way to predict which patients will benefit the most from SBP treatment.

2) Who is doing the study?

Dr. Steven Levine is in charge of this study at this location. About 40 people will be in the study at this location. About 1280 people will be in the study around the country. This study is being sponsored by The National Institute of Neurological Disorders and Stroke (NINDS), a branch of the National Institute of Health (NIH).

3) 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. The study drug, Nicardipine, is commercially available, and it is standard therapy for your condition. 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 co-payments or deductibles.

4) You cannot be in this study if:

You are pregnant and/or breast feeding

5) Pregnancy:

If you are pregnant and/or breast feeding, you cannot participate in this study. This is because the mother could transfer the study drug, nicardipine, to the developing fetus or baby. Nicardipine may not be safe for a developing fetus or baby. If you are a woman and you are an age where you could be pregnant, your doctor will give you a pregnancy test as part of your routine care.

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

This study involves the following three parts:

1) Screening and treatment through the first 24 hours
2) After treatment through the first 7 days or just before you leave the hospital.
3) Follow-up at 1 month and 3 months.

Screening and treatment through the first 24 hours:

This part of the study will take place in the emergency room or in the intensive care unit (ICU).

- As part of your routine care, your doctor will check your glucose level, your blood cell counts, and the salts in your blood (electrolytes). They will also check your heart by giving you an EKG test, and they will give you a pregnancy test if you are a woman and you are an age where you could be pregnant.

The activities we will ask you to do are:

- Talk about the informed consent form
- Sign the informed consent form.
- Go over the reason for being in the study.
- If you can be in the study, we will randomly put you in one of two groups. You will have a 50/50 chance of being in either group, like the flip of a coin.

  -Group 1: we will give you the study drug and we will lower your blood pressure to the standard treatment level, which is 180 mmHg.

  -Group 2: we will give you the study drug and you will get blood pressure treatment that lowers your blood pressure to less than 140 mmHg, which is more than the standard treatment level.

- We will give you the study drug as an IV for up to 24 hours.
  - We will change the amount to keep your blood pressure in the right range.
- We will take your blood pressure every 15-30 minutes while you are on the study medicine.
- You will take another CT scan of your brain 18-24 hours after you start the study medicine.
- We will go over your medical records to look at:
  - Your medical history of stroke or other brain issues you may have had.
  - Results of your lab tests and EKG
  - Medicines you have taken in the past or are taking now.

- Results of your MRI (if the doctor treating you wants you to have this test)

- We will copy this information from your medical records and record it in the study database
- We will not let anyone else know any personal details about you.

<u>After you get treatment with the study drug through day 7 or right before you leave the hospital</u> (whichever happens first):

The following will happen at 3 different times:

1) 48 hours after your stroke
2) 72 hours after your stroke
3) 7 days after your stroke or when you are discharged from the hospital (whichever happens first)

The activities we will ask you to do while you are in the hospital at these 3 different times are:

- We will go over your medical records to look at:
  - Your blood pressure readings
  - Results of any lab tests your doctor may have given you as part of your routine care.
  - Any other procedures your doctor may have given you as part of your routine care.
  - Results of your MRI (if the doctor treating you wants you to have this test)
- We will copy this information from your medical records and record it in the study database
- We will not let anyone else know any personal details about you.

<u>Follow-Up: 1 month and 3 months after your stroke:</u>

- Telephone interview at 1 month
  - A member of the study team will call you for a 20-30 minute talk about the things you have been doing everyday since your stroke.
  - They will ask how you feel, and if you have any side effects or problems with your health.
  - We will write down this information without letting any one else know any personal details.
- Visit with a doctor at 3 months (this is standard care for stroke patients)
  - The study doctor will give you a physical examination, where they will check to see how your stroke has affected you by administering a stroke scale.
  - They will take your blood pressure and administer an exam to see if you have any disabilities by asking you about the things you have been doing everyday.
  - The doctor will see if you are having any side effects or problems with

your health.
- You will fill out a questionnaire that asks about your quality of life which will take 10 minutes to complete.
- We will go over your medical records to look at:
  - Your blood pressure readings
  - Results of any lab tests your doctor may have given you as part of your routine care.
  - Any other procedures your doctor may have given you as part of your routine care.
  - Results of your MRI (if the doctor treating you wants you to have this test)
- We will copy this information from your medical records and record it in the study database
- We will not let anyone else know any personal details about you.

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

Some risks of taking the study medication (nicardipine) are:

Occasional risks (about 1 in 10 people will experience these risks)
- Low blood pressure
- Increased heart rate
- Headaches
- Nausea
- Vomiting

Rare risks (less than 1 in 20 people will experience these risks)
- Allergic reaction
- Low blood flow in organs of the body (hypoperfusion)
- Change in level of consciousness/awareness
- Weakness in a part of the body
- Numbness in a part of the body
- Low blood flow in the heart
- Decrease in amount of urine

Even with blood pressure treatment, it is possible that your stroke symptoms may get worse. You may also have a risk or side-effect we don't know about yet. You might develop a new symptom or health issue. If you do, you should tell the study doctor immediately.

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

We cannot promise that you will benefit from being in this study. However, possible benefits include better general health after your stroke, and less risk of death.

Subjects receiving the intensive blood pressure treatment in the previous study tended to do better than those getting the standard treatment. A general benefit of this study is more knowledge about treatment of strokes where there is bleeding in the brain.

9) What are your other choices?

If you do not want to be in the study, you have other choices. You can choose to have the standard treatment for bleeding in the brain. This means your blood pressure is reduced to less than 180 mmHg.

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 Levine at 718-270-3188. If you think you have been injured because of the research, you should call Dr. Steven Levine at 718-270-3188.

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.

Call 718-270-2121 24 hours a day and ask for Dr. Steven Levine 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 information will be kept in a secure, locked, 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.

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 history of stroke.
- Information obtained from this study, including brain CT scans, blood pressure measurements, EKG results, and the results from the questionnaire about quality of life.

The researchers, their staff and the staff of SUNY Downstate Medical Center 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 sponsor(s) of the study – National Institute of Neurological Diseases and Stroke
- The Food and Drug Administration
- The Data Safety Monitoring Board that reviews the safety of this study
- The Institutional Review Boards of SUNY Downstate Medical Center and the federal Office for Human Research Protections.

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

You need to know that some of the individuals or groups mentioned above are not obligated to protect the privacy of your IIHI. For example, the National Institute of Neurological Diseases and Stroke does not have the same obligation to protect your IIHI under the federal privacy laws.

Some IIHI that is obtained in this study will not be shared with you. This includes which study treatment group you will be in. 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: Dr. Steven Levine, SUNY Downstate Medical Center, Department of Neurology, 450 Clarkson Ave, 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 may have 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 Levine or one of the study staff members.

Dr. Steven Levine or the sponsor 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 directions given to you by the study doctor or study staff

13) What else do you need to know?

If we find out anything new that might affect your decision to stay in the study, we let you know.

There is always a possibility, although small, that you might be injured by being in this study. If you are, emergency care will be available and provided. SUNY Downstate Medical Center does not have a policy to pay you directly if you are injured by being in the study.

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 Notice of Privacy Practice.

Signature of Subject (or Legal Guardian)	Date	Print name
If Legal Guardian or family member, state relation to subject		
Signature of Person Obtaining Consent	Date	Print name
Signature of Witness	Date	Print name
Legally Authorized Representative	Date	Print name