UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Brain Attack Surveillance in Corpus Christi

Principal Investigator: Lewis Morgenstern, MD

Co-Investigators: Lynda Lisabeth, PhD, Devin Brown, MD,

Darin Zahuranec, MD, James Burke, MD, Deborah Levine, MD

GENERAL INFORMATION

We are conducting research to learn about stroke in your community. You were selected to be interviewed because you have had a possible stroke. You and/or your relative can take part in this interview. Taking part in this interview is completely voluntary. You may stop the interview at any time. Choosing not to be in this study will not affect your care in any way. There is no charge to you or your health insurance for participating. You are eligible to receive $50 for your participation in the entire study.

If you decide to volunteer the following will happen:

1. You will be interviewed in-person about your past medical history and factors that may influence the reasons why people have strokes. This interview will take about 30 minutes. You are eligible to receive $25 at the completion of this interview.

2. Study investigators will further review your medical record related to your current illness.

3. We would also like to interview a relative or friend of yours about you. This person will be asked questions about your memory and thinking prior to your current illness. If you check "yes" below, you are agreeing to allow us to interview a specific friend or relative of yours and you will provide the name of this person and contact information if necessary (check one).

☐ **No** ☐ **Yes** Name of person: _____

Contact information:_____

If you agree to provide the contact information but are not able to provide this information at the time of your interview, we may telephone you to acquire this information.

4. We may ask you if there are any individuals who would serve as your primary caregiver if you needed care. If you identify a primary caregiver they will be approached for participation in a separate study.

5. If you qualify, you will be interviewed again approximately 90 days after your current illness. The interviews will take place in your home or another convenient location for you and will take

approximately 45 minutes. You will be asked questions about your recovery and use of medications since your illness. Some study participants may be asked to participate in memory testing during the interview. If we find that you have enough difficulty with your memory or thinking that it interferes with your daily activities, we will notify you. If you wish, we will also send this information to your primary care doctor (if his/her information is included in your medical chart or if you provide it to us). If you do not have a primary care doctor, or if his/her contact information is not available to us, we will mail your results to you. You may be asked questions about relatives or friends that are helping you with your recovery. You may have a brief neurological examination performed. We may ask to measure your blood pressure. If you agree, approximately three measurements will be taken during each interview. You are eligible to receive $25 at the completion of the outcome interview We will also contact you approximately midway between each interview as a reminder, and again approximately two weeks prior to the interview to schedule the date and time. If we are unable to contact you, the relative/friend you named above or recorded in your medical record will be contacted to see if he/she is aware of your location.

6. We will contact you (or your family member) every two weeks over the next 90 days via telephone to ask you questions regarding where you are residing, any rehabilitation services that you have received, and whether you have been readmitted to the hospital. Each telephone call should take no longer than 5 minutes.

Information About Risks and Benefits:

The study does not require you to have any additional medical tests other than those you would ordinarily have as part of the standard care for your illness. The study also does not provide or require any experimental therapy. Some people may find the memory questions interesting, stressful or tiring. We will give you a chance to take breaks in between questions. Our staff will provide local mental health resources to all participants. In the rare event that a participant shares with the interviewer plans to harm oneself or others the participant may be referred to mental health professionals at Bayview Behavioral Health Hospital. If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies. When we measure your blood pressure you may experience a mild discomfort from the arm cuff.

Information collected during the study will be maintained in a research file not generally accessible to people other than the researchers. While every reasonable effort is made to safeguard your protected health information (PHI), there is a minimal risk of loss of confidentiality due to the disclosure of PHI. There may be no direct benefits to you for participating in this study. Over the course of the study many subjects have told us that they enjoyed participating and providing their input. Your participation will help doctors better understand strokes so that they may better help patients in the future.

Your collected information may be shared with National Institutes of Health (NIH), the sponsor of this project. With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies. Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future

research studies without additional informed consent. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

Signing this form gives the researchers your permission to obtain, use, and share information about you for this research, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital records, including test results (imaging, blood tests, etc.)
- All records relating to your possible stroke and the treatment you have received

University of Michigan policies require that private information about you be protected. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. To protect your privacy, you will be assigned a study identifier used on your research records instead of your name. Research records with your personal health information will be kept in a separate file that does not include names, registration numbers or other information that is likely to allow someone other than the researchers to link the information to you.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. For example, the University, Food and Drug Administration [FDA], study sponsors and/or other government officials may need the information to make sure that the study is done properly or to analyze the results of the study. The researchers may need to use the information to create a databank of information related to stroke.

If your information is shared with others outside of the research team or University, as described above, it may no longer be protected by federal privacy regulations issued under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. However, the researchers will keep all records they collect confidential as required by federal, state and local law, as well as university policy. Your permission will not expire unless you cancel it. You may cancel your permission at any time by contacting the researchers listed below.

CERTIFICATE OF CONFIDENTIALITY

This project is funded by the NIH and holds a Certificate of Confidentiality (CoC) that offers additional protections for your identifiable research information and records. The most important protection is that members of the research team cannot be forced to disclose or provide any of your private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission. Disclosure of your research information may only occur in limited specific instances. For this study, the researchers may share your information with appropriate authorities if they learn about child or elder abuse, or neglect or harm to self or others. For the full detailed description of the CoC protections and exceptions to those protections, please request an additional information sheet from the study staff.

Your signature in the next section means that you have received a copy of this "Consent to be Part of a Research Study" document. (Note: In addition to the copy you receive, a copy of this document will be stored in a separate confidential research file.)

CONTACT INFORMATION

To find out more about the study, ask a question or express a concern about the study or if you feel you have experienced any harm from the study contact one of the following:

Principal Investigator: Lewis Morgenstern, MD 1500 East Medical Center Dr, SPC#5855 Ann Arbor, MI 48109 Telephone: 734-615-7390	Field Office Director: Belinda Zuniga 4646 Corona Drive Ste. 155 Corpus Christi, Texas 78411 Telephone: 361-853-1945
University of Michigan Compliance Help Line at 1-888-296-2481 or if you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481	University of Michigan Medical School Institutional Review Board (IRBMED) 2800 Plymouth Road, Building 520, Room 3214 Ann Arbor, MI 48109 734-763-4768 E-mail: irbmed@umich.edu

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Signature of Proxy _____ Date: _____

Name (Print legal name): _____Phone: _____

Address: _____

Check Relationship to Subject:

☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal Guardian ☐ Other:

Reason subject is unable to sign for self:_____

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____Title: _____

Signature: Date: