Department of Veterans Affairs	**VA Research Consent Form**

Subject Name:		**Date:**	
Title of Study:	Stroke Self-Management: Effect on Function and Stroke Specific Quality of Life IRB Study #1204008443		
Principal Investigator:	Teresa Damush, PhD	**VAMC:**	Roudebush VA Indianapolis

Purpose of study and how long it will last:

You are invited to participate in a research study designed to help us understand how a stroke prevention program intended to help improve control of medical conditions that increase the risk of having another stroke compared to standard care. Patients who have had a stroke or TIA are at risk for having another stroke. In fact, over 14% of stroke survivors will experience another stroke within a year. Some stroke risk factors are not changeable, like age, race and heredity, while others such as lack of exercise, smoking, weight and high blood pressure are changeable. The changeable risk factors are best managed through both lifestyle changes (for example, diet and exercise changes) and medications. The overall purpose of this research study is to develop and test a stroke risk management program to help patients improve control of the health conditions that increase their risk of stroke. This is a three year study, but the time you are involved in the study will only take 12 months.

Description of the study including procedures to be used:

If you agree to participate, you will be one of 102 veterans who will be participating in this research locally and 78 at Jesse Brown VA in Chicago, IL. In addition to veterans 252 non veterans will be participating in this research from IU Health Methodist Hospital or Eskenazi Hospital. You will be given the opportunity to be consented via telephone and sign the written informed consent statement and HIPAA form by mail if you cannot make it in-person. You will be interviewed by research personnel about such things as your knowledge of your stroke risk factors, your quality of life and your expectations after a stroke or TIA. You will be randomly assigned (like flipping a coin) to either the intervention or the usual care group. *You will have a 50% chance of being assigned to either group*. You cannot choose which group you will be in.

If you are assigned to the intervention group, you will receive the stroke risk factor management program, including information on medication management and lifestyle and behavior changes you may need to make in your life to decrease your risk of having another stroke. A stroke prevention program is a collection of materials including written materials like pamphlets and brochures, videotapes, and training guides for stroke survivors and for the doctors that provide care for them. Other tools that may be used in a stroke prevention program include things that help you monitor your medical symptoms at home like blood pressure machines or blood sugar monitors and messaging devices that allow you to report your symptoms from home to a health care provider. During your 12 months in the study program you will work with a care manger to address your changeable risk factors. In the first 3 months of your participation in the study, you will receive 30-45 minute phone calls from a care manager every 2 weeks to discuss setting goals to improve control of your stroke risk factors and will receive support and training from the care manager to help you meet those goals.

At the time of randomization to the intervention, you will be encouraged to attend quarterly stroke/TIA support group. These groups will last 1-1.2 hours at the Roudebush VAMC. There is a potential loss of confidentiality while participating in these groups. In addition to the quarterly Stroke/TIA support groups, in months 4-6 you will receive a monthly phone call from the study case manager in order to uphold your efforts to reduce your stroke risk factors. After your 12 month interview, you may also be asked to participate in a small group session or exit interview after you finish the stroke prevention program. If you attend at least 1 Stroke/TIA Support Group while in the study, you will also be invited to attend the Stroke/TIA Support Group after your completion of the 12 month assessment/interview. We will randomly (like flipping a coin) choose some research participants for these discussions or interviews. Group discussions will last 2 hours and will be held at the Roudebush VAMC in Indianapolis. This group is informal and you may share as much or as little information as you feel comfortable. This group discussion will focus on your experience in the stroke risk management program, what you liked and didn't like about the program and any suggestion you may have to improve the program before it is made widely available to all veterans. During these group discussions someone will be taking notes and the session will be audio recorded. We need to audio record these sessions so that after everyone has gone home we can take detailed notes. The audio recordings will be destroyed after the study. You may choose not to participate in this part of the study without affecting your care in any way. There is a risk of possible loss of confidentiality during the support and focus groups since the groups will primarily consist of stroke/TIA patients. At the beginning of the support and focus groups, study staff will request the group members to keep all disused information confidential. If you are unable to come to the hospital to complete one of the questionnaires or to attend a group session, we may schedule an appointment with you at your home.

If you are assigned to the usual care group**,** you will receive Roudebush VA standard stroke education during your stroke/TIA hospitalization and during the 12 months you participate in this study. Usual care group subjects will be offered the study self management packet of printed materials after they complete the 12 month survey.

Both usual care and intervention group participants will be asked to complete study questionnaires 3 months, 6 months and 12 months after enrolling in the study. Your responses to these questionnaires will help us evaluate how you are doing and how you feel about your ability to manage your stroke risk factors. Depending on your responses, these questionnaires will take 30-60 minutes. Participants may choose to complete these study questionnaires by phone or in person at Roudebush VA. At the completion of the 12 month assessment/interview, all participants in the intervention and control groups will be asked as to whether or not they are interested in attending the Stroke/TIA Support group. Only those who say yes will then get invited for subsequent support group meetings.

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Study staff will take all precautions to keep your medical information confidential. We cannot guarantee absolute confidentiality. All written and audio tape study data of participants will be kept in locked cabinets and behind locked doors in the research coordinator's office at Roudebush VA. All participant data stored in an electronic format will be place on a secure Roudebush VA server. Only authorized study personnel will be able to get access your study information. No personal information will be used to identify you when we look at the data. Your name or other personal information will not be used in a publication.

Risks:

While in the study, the risks of completing the survey are being uncomfortable answering the questions. You may tell the researcher you feel uncomfortable and you do not have to answer any question that makes you feel uncomfortable. If you are in the intervention group and participate in group sessions there is a slight risk of loss of confidentiality from the other group participants. Group participants will be advised to keep all information shared during the group sessions confidential but the study cannot guarantee absolute confidentiality.

Benefits:

The benefits to participation are the potential improvement in your knowledge of stroke risk factors (both groups) and an increased ability to manage your stroke risk (intervention group). Treatment with the stroke risk management program may improve your stroke risk factors. This may provide relief from symptoms and improve your quality of life. However, neither of these benefits is guaranteed. Although you may not directly receive any medical benefits from participating in this study, the knowledge gained from this study may help others should the results prove useful.

Alternate Courses of Action or treatment:

Instead of being in the study, you have the option to not participate in this study. You will receive usual care, follow-up, education and information from your doctors and nurses as they see appropriate.

Statement of Use of Research Results:
The results of this study may be published, but your records or identity will not be revealed unless required by law.

Special Circumstances:

Confidentiality:

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and in the databases in which study results will be stored. Only authorized study personnel will have access to your personal study information. All your written study information will be stored in a locked filing cabinet in the research coordinator's office at Roudebush VA. Only authorized study personnel will have access to your personal study information

Should you participate in the closing focus group discussion (Intervention group only), confidentiality is limited by how much or little information you share. This is an informal session and we only use first names. Your Roudebush health care providers will not be told what information you shared in the focus group. All focus group notes and audio recordings will be stored in a locked filing cabinet in the research coordinator's office at Roudebush VA. Only authorized study personnel will have access to your personal study information.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the investigator and his/her research associates, the study sponsor, the Indiana University Institutional Review Board or its designees, the VA Research and Development Committee or its designees, and the Office for Human Research Protections (OHRP), who may need to access you medical and/or research records.

Research Subject Costs:

1. There will be no costs to you for any of the treatment or testing done as part of this research study. Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.

2. The study is sponsored by the Department of Veteran Affairs.

3. You will not need to pay for parking at Roudebush VAMC.
4. You will not be required to pay for medical care or services received as a participant in a VA research project except as follows:

Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are **not** part of this study.

Compensation & Treatment for Injury:

1. You will receive payment by gift card for taking part in this study at completion of each of the following assessments: Baseline = $15, 3 month = $15, 6 month =$15, and 12 month = $15. If you complete all 4 study assessments you will receive $60 in gift cards.
2. The VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This does not apply to: (1) treatment for injuries due to noncompliance by a subject with study procedures; or (2) research conducted for VA under a contract with an individual or a non-VA institution.
3. Financial compensation for research-related injuries is not available. However, by signing this form, you do not give up your legal rights to seek such compensation through the courts.

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RESEARCH SUBJECT'S RIGHTS:

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits. You will receive a copy of this signed consent form.

In case there you have medical problems during your participation in this study, contact the Roudebush VA Patient Response Center during normal business hours at 317-988-4498, to schedule an appointment with your primary care provider. For medical problems after normal business hours, please contact the neurologist on call at 317-273-5000. If any medical problems occur in connection with this study, the VA will provide emergency care. Please contact the study project coordinator at 317-988-4388 or 317-988-4892 if you believe you have side effects from the self management program.

Please direct questions about the consent process and the rights of research subjects to the VA Customer Service Office at (317) 988-2602. For questions about your rights as a research participant or complaints about a research study, contact the IU Human Subjects Office at 317/278-3458 or 800/696-2949. If you have any questions about the research study or want to check the validity, discuss problems, concerns or obtain information or offer input, please call the Research Office at 317-988-3032.

The study has been explained to me and all of my questions have been answered. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained.

Subject's Signature	Printed Name of Subject	Date

Signature of Person Obtaining Consent	Printed Name of Person Obtaining Consent	Date

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