Introduction:

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish, including your friends, family, and family doctor. Participation in this study is voluntary.

1. Purpose of study and how long it will last:

You are being asked to participate in this research study because you have had a stroke and are still able to walk but your walking has been affected. The purpose of this study will investigate the use of a powered exoskeleton called "Keeogo". Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

The purpose of this study is to determine how effective training using a device called Keeogo can be on your ability to walk. The Keeogo is a robotic device that can be worn by a person with some paralysis due to stroke. The goals of this study are as follows:

- Determine the change in the ability to squat as measured by the Five Times Sit to Stand Test (5xSTS), while wearing and not wearing the powered exoskeleton.
- Determine if training for 3 months (36 sessions) can improve knee range of motion (ROM) and if it will increase the usage of the paralyzed leg (LE loading) while you walk with and without the powered exoskeleton.
- Determine the energy used (energy expenditure) while walking with and without the powered orthotic exoskeleton at baseline and after 36 sessions of training.
- Determine the how much function (squatting, knee ROM, paretic LE loading and energy expenditure) you retain after 1-month of no training without the device.

- Determine differences in QOL measurements (SF36 and Stroke Specific Quality of Life Scale [SS-QOL]) after 36 sessions of training
- Determine differences in body composition and bone mineral density (as measured by DXA) after 36 sessions of training.
- Determine changes in resting brain activity (as measured by EEG) after 36 sessions of training and after 1-month ceasing training with the device.

Background/Purpose: Functional impairment of the lower limbs is a common consequence of stroke. The resulting mobility limitations have a major negative impact on patient's quality of life and prognosis. Early recovery of mobility and possibly motor function is therefore an essential element of the rehabilitation regimen. Assisted training has been shown to help with rehabilitation and improve patient outcome.

Robotic exoskeleton technologies have the potential to enhance mobility while using these devices. They may also help improve functional recovery for people with neurological conditions such as stroke. The Robotic exoskeleton used in this study is called Keeogo™ and is a powered walking assistance device. This device is based on B-Temia's Dermoskeleton™ technology (***Figure 1***). It has a motor by the knee to help its movement. Preliminary data on patients with several conditions have shown that the device can improve patient mobility and functional capacity. The data from clinical trials have suggested that the device may prove beneficial in improving mobility and functional ability, and that the device has been shown to be safe.

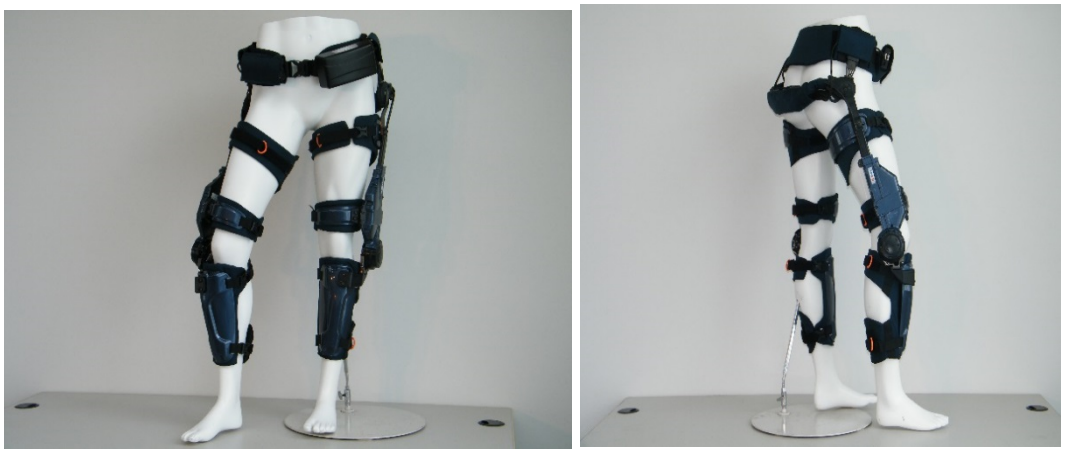

Figure 1 – B-Temia's Keeogo™ Dermoskeleton

This device does not yet have marketing approval by the Food and Drug Administration (FDA). This device is considered a Class II Powered Exoskeleton. This study received funding from a VA RR&D Small Projects in Rehabilitation Research (SPiRE) grant.

You are being asked to participate in this study to see if training with this device is more effective than training without this device over 36 sessions for approximately 3-months time. You will be one of 25 participants for the study. Ten people will not qualify, 10 people will be randomly assigned to train with the powered exoskeleton device and 5 people will train without the exoskeleton device. You qualify for the study if you fit the following criteria:

Inclusion Criteria:

1. Males and female between 18 and 89 years old;
2. Have difficulty moving the leg from one side of the body due to stroke (>6 months);
3. Able to walk between 0.15-0.75m/s
4. Self-reported limitations to mobility and walking activities due to paretic side knee stiffness and loss of range of motion;
5. Weight under 250lbs
6. Desire to increase daily activity levels; and

7. Able and willing to commit to participation and follow directions and communicate basic needs.

Exclusion criteria:

1. Neurological paralysis causing an inability to stand, weight bear or take stepping movements;
2. Fixed contractures resulting in limited range of motion in the hip, knees, or ankles that prevent sitting, standing, walking, and/or squatting activities;
3. Modified Ashworth Scale for spasticity greater than 3 in the lower limbs
4. Able to walk at a normal walking speed (1.4 m/s, 3.2 mph) or better during the 6MWT;
5. Anthropometric incompatibility with the device
   a. Femur length less than 36 cm or greater than 45 cm;
   b. Upper thigh circumference less than 55 cm or greater than 75 cm;
   c. Lower thigh circumference less than 27 cm or greater than 40 cm;
   d. Calf circumference less than 33 cm or greater than 49 cm;
   e. Ankle circumference less than 27 cm or greater than 40 cm;
   f. Shin length less than 26 cm;
   g. Waist circumference less than 71 cm or greater than 107 cm;
6. Any medical complication or co-morbidity as judged by the study physician to be contraindicated for wearing the device or walking (e.g., cardiovascular disorders, pressure ulcers, open wounds, lower limb vascular disorders, or other medical conditions); and
7. Pregnant or planning to become pregnant (Females only).

2. Description of the Study Including Procedures to be Used:

If you consent to participate in this research study, you will be asked to visit the James J Peters VA Medical Center for a total of 40 study visits. The time you will spend to complete this study is approximately 4 months. This is the breakdown of the visits:

- 1 visit for screening evaluations
- 1 visit for baseline evaluations
- 36 visits for the training program (3 months to complete) [this will include 2 visits for mid-point evaluations]
- 1 visit 1-month Post training evaluations

- 1 visit a month after completing the post training evaluation.

The breakdown of study participation and a time line of testing is presented in Table 2.

Screening Visit:

Your first visit is for screening purposes. This is to determine if you are willing and able to participate in this study. You will be asked several questions about your general health and your specific medical condition and use of medications. Your ability to continue to participate will be tested according to the following:

- Physician evaluation and medical history
- Walk less than 500 meters in 6 minutes (6MWT)
- Evaluation of your ability to move your hips, knees and ankles to ensure you are able to sit, stand, walk and squat
- Ensure that you can fit in the powered exoskeleton

Table 2: Timeline for testing and training

Schedule of Procedures and Testing										
Week:	-2 to -1	-1	1-4		4-5	5-8	8-9	9-12	12-13	16
Phase	Pre Screen	Screening /Baseline Testing	Training		Assessments	Training	Assessments	Training	Post Assessments	1-Month Follow-up
Chart reviews	x									
Consent	x									
Medical History/ Demographics		x								
Fugl-Meyer		x			x		x		x	x
EEG		x			x				x	x
DXA		x							x	
QOL(SF36 and SSQOL)		x							x	
Training session number			1-3	3-12		12-24		24-36		
Assessments with out Keogo (both Control and Exoskeleton group)										
5xSTS		x	d	d	x	d	x	d	x	x
Gaitrite		x	w	w	x	w	x	w	x	x
F-Scan		x			x		x		x	x
Energy Expenditure		x			x		x		x	x
Knee range while walking		x	w	w	x	w	x	w	x	x
10mWT		x	d	d	x	d	x	d	x	x
TUG		x	w	w	x	w	x	w	x	x
6MWT		x	d	d	x	d	x	d	x	x
Assessments with Keeogo (only Exoskeleton Group)										
5xSTS			d	d	x	d	x	d	x	
Gaitrite			w	w	x	w	x	w	x	
F-Scan			x		x		x		x	
Energy Expenditure			x		x		x		x	
Knee range while walking			w	w	x	w	x	w	x	
10mWT			d	d	x	d	x	d	x	
TUG			w	w	x	w	x	w	x	
6MWT			d	d	x	d	x	d	x	

Key: w=weekly; d=daily; x=once

Randomization:

If you choose to participate and meet the study criteria, it is important to note that you will be randomly assigned (like the flip of a coin) to one of two groups. The groups are either the Intervention group or the Control group. Both groups will participate in a 36-session training program at the James J Peters VAMC focused on improving your ability to walk, stand-up, sit-down and be mobile. Those randomly assigned to the Intervention group will use the powered exoskeleton during these sessions and those randomly assigned to the Control group will not. There will be twice as many people in the Intervention group as the Control group, therefore you have double the chance of being assigned to the Intervention Group than the Control group. Neither you nor any member of the study team can choose, control or predict to which group you are assigned.

Baseline Assessments:

Baseline assessments that do not involve the exoskeleton will be obtained prior to training in both groups. Baseline assessments, which involve the exoskeleton (for the Intervention Group only) will be obtained during the first three sessions after you have been correctly fitted and acclimated to the exoskeleton. Therefore, the experimental group will be asked to perform these tests twice, once with the powered exoskeleton and once without. The control group will have these measurements obtained only once prior to training. The description of all the tests are as follows:

The Fugl-Meyer Assessment Lower Extremity (FMA-LE): This test will be used as a general score of lower extremity motor and sensory function/post-stroke recovery.

Five times sit to stand (5xSTS): This test is used to see if there is any improvement in your ability to squat (LE Strength). This test is performed using a standard free-standing chair with a straight back, solid seat and a seat height of 17 inches. You will be instructed to stand up and sit down as quickly as possible for 5 times. You will place your hands on your lap and will not use them throughout the procedure. You will lean your back against the

chair's backrest at the end of every repetition. The time to complete the test will be recorded and will start once your back leaves the back rest and will stop once the back touches the back rest for the 5th time.

Gait Assessments: Assessment of gait changes will be performed using the GaitRite Carpet (CIR Systems Inc), the F-scan foot pressure system (Tekscan) and the instrumented goniometer). The GaitRite measurement will be obtained by walking over a carpet equipped with sensors, which provide information regarding cadence, step length and time spent on each foot. The F-Scan foot pressure system requires you to walk with a disposable insole, which is cut to fit the inside of their shoe. The disposable insole contains an array of sensors, which provide a continuous pressure profile of each foot during ambulation. This system will measure the percentage of total body weight loaded during the different segments of the stance phase (heel-strike, stance and toe-off) as well as the body weight loaded throughout the gait cycle for each lower extremity. An electronic goniometer will be strapped to each lower extremity for independent and simultaneous measurement and recording of knee ROM.

Energy Expenditure: You will be asked to wear a face mask attached to a portable metabolic cart. Measurements of oxygen uptake (VO_2), heart rate (HR) and respiratory rate (RR) will be assessed and recorded. These measurements will be acquired during 6 minutes of quiet sitting (rest) followed by ambulating at a comfortable, self-selected pace for 6 minutes.

Quality of life Measurement (QOL): General changes in QOL will be assessed using the SF36 and Stroke Specific Quality of Life (SSQOL) scales. These measurement tools are a list of questions that ask you about how you perceive different aspects of your quality of life.

Bone Density and Body Composition: A dual energy x-ray absorptiometry (DXA) scan for regional and total body fat, lean and bone tissue masses will be performed two times: at baseline and post testing. You will be asked to lie on a padded tabletop. A machine will use

a very low dose radiation which will tell us the amount of muscle, fat and bone you have in your body. The maximum radiation you will be exposed to for each scan is as follows:

Scan Type	Entrance Dose	Effective Dose	Scan Time
Total Body	6 µGy	8.62 µSv	739 sec
Dual Femur	329 µGy	12.3 µSv	212 sec
Knee	34 µGy	2.0 µSv	54 sec

We estimate all of these DXA measurements combined will sum up to less than 35 µSv of absorbed radiation. This measurement is minimal even when compared to a routine chest x-ray which has an approximate dose of 60 µSv. In addition, the average person in New York City receives approximately 3000 µSv/year. Therefore, you would have to have all these tests done 100 times to receive an equivalent dose.

Electroencephalogram (EEG): You will undergo resting-state electroencephalography (EEG). During the EEG you will be asked to sit in a chair with an EEG cap on your head. An EEG cap resembles a swim cap with 64 electrodes embedded in it. We will ask you to brush your hair and scalp to prepare your skin and detangle your hair. This is to make sure that the electrodes can make good contact with your scalp and record electrical signals accurately. The EEG measures your electrical activity; it does not put any electricity into you. We will place salt gel inside the electrodes, and you might feel that wetness on your scalp

You will be asked to be calm and still while we record the signal. These tests will be explained to you and you will be able to ask questions before you begin. You will be asked to close your eyes for 10- minutes, relax but not to sleep, while we record EEG data.

Training Sessions:

You will be asked to visit the JJPVAMC for 36 training sessions, 3 times per week for about 3 months. Those in the exoskeleton group will train using the Keeogo powered exoskeleton and those in the control group will train without the exoskeleton using their conventional assistive devices. Training sessions will be progressive, with duration to tolerance for a minimum of 20 minutes and a maximum of one hour. Training will consist of mobility activities affecting daily life including: walking; squatting (or getting in and out of a chair);

bending, kneeling or stooping (for picking an item up off of the floor); and ascending and descending stairs. You will not be asked to perform any skill you are not comfortable to perform. Sessions will be monitored and tailored to you, based on your functional ability and to ensure your safety. You will be allowed to take as many breaks as needed during each session. Every session the 5xSTS, 10MWT, and 6MWT will be recorded. Once every week the gait assessments (6MWT, 10MWT, TUG, Gaitrite, F-scan, and knee range) will be performed.

Description of the Exoskeleton:

Only those randomized into the powered exoskeleton group will be using the powered exoskeleton called Keeogo™ (B-Temia Inc., Quebec City, QC, Canada). This device is designated by the FDA as a powered exoskeleton. It is designed for people who have difficulty walking and/or need assistance with movement of the knee (Figure 4). This device does not restrict movement and only provides assistance at the knee during extension and flexion during ambulation, standing up, sitting down and when going up or down stairs. It is not intended for people who cannot use one or both of their legs because requires some active movement for it to work. The Keeogo™ weighs about 15lbs and consists of a combination of soft material and rigid structure that can be adjusted. It can be changed to fit different people and it is attached to both of your legs.

Figure 4: Keeogo

It works by using motors which can be adjusted to provide more help or less help depending on each person. The assistance you get on each leg can be adjusted separately and in two ways. You can adjust the level at any time using the control unit on your hip. The second way is with the trainer who has a tablet interface that can adjust the configuration of the device. The device will only help once you start to actively perform a movement and will not completely control movement. You will be able to the movement whenever you would like. You can even stop the movement in the middle of a gait cycle just by deciding to stop moving your leg.

Midpoint Evaluations

The baseline assessments (Fugl-Meyer, 5xSTS, Gait Assessments, Energy Expenditure, and QOL measurements) will be obtained on the 12 and 24 sessions while using the powered exoskeleton for the exoskeleton group only. These tests will be repeated for all participants without the exoskeleton for both groups after completion of the 12th and 24th sessions. The EEG will be done on the 12th session, but not the 24th.

Post Training Assessments:

All of the baseline assessments (Fugl-Meyer, 5xSTS, Gait Assessments, Energy Expenditure, and QOL measurements) will be obtained on the 36 session while using the powered exoskeleton for the exoskeleton group only. These tests (as well as the DXA and EEG) will be repeated for all participants without the exoskeleton for both groups after completion of the 36th session.

1-month follow-up Assessment:

All participants (control and experimental) will be asked to return 1-month after completing the Post Training Assessment. During this visit all the outcome measures will be repeated (Fugl-Meyer, 5xSTS, Gait Assessments, Energy Expenditure, QOL measurements, and EEG) without the exoskeleton for both groups to assess retention of functional gains.

Post Study Participation for the Control Group

After the completion the 1-month follow-up assessment, those who were randomized to the control group will be given the opportunity to train and use the Keeogo device for a 2-week period for 1 hour per session, 2/3 sessions per week. No study outcome data will be collected during this post study training. This component of the study is optional.

3. Description of any Procedures that may Result in Discomfort or Inconvenience:

As with any investigational study, there may be adverse events. This study involves an FDA investigational device and there may also be some risks that are currently unknown. The following list contains potential discomforts or inconveniences related to study procedures:

If you are wearing the exoskeleton, you may experience discomfort associated with. You may experience some skin pressure or friction that can lead to bruising, pain, or unusual swelling. Device use may even lead to skin breakdown or abrasions. This risk will be minimized by a thorough skin check performed by experienced research personnel during each training session. Adjustments to the device fit and additional padding will be assessed to decrease the risk of skin breakdown. The device used in this study will not be available to you after you complete this study.

During training sessions, you may experience some blood pressure instability. This is associated with physical activity during testing and training procedures. The risk associated with blood pressure alterations are reduced by your ability to take as many breaks as needed. An assessment of your level of effort is also determined. Study staff will also make an assessment of blood pressure and heart rate during the training. Activity will be stopped in the event of instability of vital signs and as recognized by experienced research personnel.

Since this research may have unknown effects on an unborn child and should not be done during pregnancy, it is necessary for a pregnancy test to be done first. To your knowledge you are not pregnant at the present time. You also agree to avoid becoming pregnant (use contraceptives, take precautions against becoming pregnant, etc.) during this study.

4. Expected Risks of Study:

Participation in this study has a few risks that you should be made aware of. As you will be training, there is a chance that you could become unstable and fall. The risk of falling is minimized by having experienced research personnel with you during your study visits. You will also be able to use any conventional assistive device (cane, walker or other) that you need. You will be able to use these devices regardless of the group you are in and weather or not you are using the Keeogo powered exoskeleton. The risk of falling is minimized by excluding individuals with stroke who cannot stand and ambulate.

It is possible that the device itself could malfunction. The device has built-in mechanical stops to limit the devices ability to move through abnormal ranges of motion. In addition,

the activities that will be performed with the device will be performed by trained research personnel to monitor device function during use.

If you walk using the powered exoskeleton, the device may make you feel unstable or cause tripping. This risk is minimized by allowing you to use an assistive device such as a walker or cane. In addition, the settings of the device can be adjusted to reduce the instability.

There are additional risks such as skin abrasions / or irritation. This may be caused by rubbing from the device or by the strapping. Effort by the staff will be made to appropriately fit the device and add additional padding in order to reduce this risk.

You may have some peripheral edema or swelling of the legs.

There may also be other risks that are unknown and unforeseen.

If the research staff observe that you are unsafe while using the device or during general physical activity the training session will be terminated. If the session was shorter than 20 minutes, it will not be counted as a session and you will be asked to repeat the session. If you continue to experience sessions that are unsafe, you may be withdrawn from participation in this study.

If you become pregnant during your participation in this study, you will be withdrawn. There may be risks to you or to the embryo or fetus, if the you are or become pregnant that are currently unforeseeable.

5. Expected Benefits of the Study:

There are possible benefits of taking part in this study such as improvement in your mobility and improved function of your legs. You may see that the training helps you stand up and sit down with less effort. You may also find that you are more mobile. The potential for this benefit may outweigh the risk mentioned in the previous section.

6. Other Treatments Available:

You could participate in physical therapy sessions or participate in another training program instead of participating in this research study.

7. Use of Research Results:

We (I) will let you and your physician know of any significant new findings made during this study which may affect your willingness to participate in this study. All data and research materials generated from this study will be restricted to research personnel located at the James J Peters VAMC. All data and records will be stored at the James J Peters VAMC according to VA regulations. Only authorized personnel will be given access to research records. Your electronic records will be stored on the VA network protected by the VA firewall. Any hard copies of research documents will be maintained, secured and stored at the James J Peters VAMC. Data that contains any identifiable information (i.e. your name, contact information, etc.) such as on this informed consent form, will be stored in locked cabinets within our research center and maintained separately from your other records. The documents that contain data collected from your participation will be coded. This means that you will have an identifier associated with your files that is unique to you. This identifier will not contain any information about you, and it will be a random number assigned to you so that the investigators know who the data belongs to. The link to breaking the code will remain secure at the James J. Peters VA Medical center. Records will be retained according to National Archives and Records Administration, in accordance with Records Schedule RCS-10-1.

□_____By initialing, you agree to be contacted by the Principal Investigator or his investigative team at a future date for additional studies being conducted at the James J Peters VA Medical Center.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

In order to comply with federal regulations, research records identifying you may be reviewed by the following: Representatives of the sponsor or sponsors VA RR&D, Authorized representatives of the Bronx VAMC (e.g. Institutional Review Board, Research

Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), Food and Drug Administration (FDA), and the Office for Human Research Protections (OHRP).

Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research subjects. If this study was initiated on or after March 7, 2012, A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

8. Special Circumstances:

A copy of your signed informed consent form and signed HIPAA authorization for participation in the study will be included in your medical health record.

9. Compensation and/or Treatment in the Event of Injury:

The VA must provide necessary medical treatment in accordance with applicable federal regulations to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees.

10. Voluntary Participation:

You are not required to take part in this study; your participation is entirely voluntary and you can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled.

11. Termination of Participation:

You may decline to participate now, or you can withdraw from the study at any time after signing this consent form. If you decline to participate or withdraw, your regular medical treatment will not be interrupted or withheld. If you decide to withdraw from the study later, you will be asked to sign a form to revoke your previous authorization.

You may be required to withdraw from the study if study staff or your doctor feels that your participation is not in your best interest. If you are not compliant with the procedures

detailed in this study, you may be withdrawn. There may be other reasons observed during your participation that is thought to affect your safety that could lead to your withdrawal.

12. Costs and Reimbursements:

As a veteran or non-veteran, you will not be charged for any treatments or procedures that are part of this study. For veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study. You will receive a payment for your participation in this study. Payments will be made by the US Treasury from funds allocated for the VA RR&D SPiRE grant # RX-003299-01 as a direct deposit to your bank account. Therefore, you will need to provide us with your bank account number and routing number to process your payment. This will be done by asking you to bring in a check that has been voided or by some other method to ensure proper documentation of banking information.

You will be paid $20 for each visit you complete up to the total 40 study visits. The visits include, 1 visit for screening, 1 visit for baseline testing, 36 training sessions, 1 visit for post testing, and 1 visit for the 1 month follow up. If you do not complete the study, you will be paid on a prorated basis according to the visits that were completed. If you complete the whole study, you will be paid $800. Payments will be made either on a monthly basis (4 total payment) or as one payment at the end of the study, according to your preference.

13. Contact Person(s):

To obtain answers to questions about the research and research subjects' rights, report or seek treatment for a research-related injury, or to voice concerns or complaints about the research contact the following (investigator/research team):

- During the Day: Ann Spungen, EdD at 718-584-9000 ext. 5814
- After Hours: Ann Spungen, EdD at 347-971-0413

To voice concerns or complaints about the research from someone outside of the research team, contact the following: I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact Mary Sano, Ph.D. ACOS/R&D Program by requesting an appointment at (718) 741-4228 hospital extension 4228, first floor in the research building, room 1F-01 If I have questions, concerns and/or complaints or to offer input.

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above. Dr. Spungen or his delegate has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law. This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature	Date
Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page)	Signature of Person Obtaining Informed Consent Date