Study Protocol

Official Title: Activating Behavior for Lasting Engagement After Stroke (ABLE)

ClinicalTrials.gov ID (NCT number): 03305731

Protocol Date: August 29, 2018

Scientific Background

Approximately 795,000 Americans sustain a stroke each year, placing these individuals at risk for recurrent stroke. One goal of post-acute rehabilitation and medical management of stroke is to reduce the risk for recurrent strokes. Reducing the risk for recurrent stroke is routinely approached by promoting health behaviors that mitigate specific risk factors for stroke. Specific health behaviors that are important for managing these risk factors include adherence to medication routines, smoking cessation, and physical activity.

Physical inactivity throughout the day can lead to cardiovascular risk factors for recurrent stroke. Prolonged time spent physically inactive, or sedentary, has been identified as a distinct risk factor for poor metabolic control, weight management, and all-cause mortality among adults, after controlling for time spent engaged in exercise. Sedentary time that is accumulated in prolong bouts with few sedentary breaks is associated with risks to cardio-metabolic health. Modifying sedentary behavior patterns after stroke may, therefore, modify cardio-metabolic risk factors for recurrent stroke. Promoting participation in daily life activities frequently requires individuals to move out of a seated or reclined position and may support the modification of sedentary behavior patterns after stroke.

Subtle impairments in cognitive functions are common after stroke. These impairments can lead to difficulty monitoring one's behavior to overcome barriers (e.g. balance impairments), and achieve participation-related goals after stroke. Difficulty monitoring and adjusting behavior, may lead to abandonment of daily life activities that require a high level of physical function (e.g. shopping at the grocery store) rather than identifying alternative strategies to return to participation in that activity (e.g. pushing the cart and planning short trips to the grocery store). When daily life activities are abandoned, they may be replaced with sedentary behavior (e.g. watching television at home while a caregiver shops for groceries).

Behavioral activation is an intervention approach that provides explicit structure for self-monitoring behavior. Behavioral activation approaches have been applied among clients with depression, dementia, brain injury, and stroke. Improvements in mood and cognitive functions and reduction in disability have been associated with behavioral activation interventions. We designed an intervention based in behavioral activation to provide explicit structure for monitoring and adjusting behavior to achieve participation in daily life activities that may break up sedentary time after stroke. Our intervention, the Activating Behavior for Lasting Engagement (ABLE) intervention, applies activity scheduling and monitoring and collaborative problem solving to client-selected goals. The ABLE intervention holds promise to promote participation in daily life activities at scheduled times throughout the day to break up long bouts of sedentary time.

Study Objectives

The purpose of this research study is to assess the feasibility and estimate the effects of a behavioral intervention (the Activating Behavior for Lasting Engagement intervention, ABLE) on sedentary behavior after stroke.

Research Question: What are the effects (sedentary behavior, participation levels) of the ABLE intervention in the chronic stroke population at post-intervention (week 10) and follow-up (week 18)?
HYPOTHESIS A: The ABLE intervention will be associated with less sedentary time accumulated in prolonged bouts over time (ActivPAL).
HYPOTHESIS B: The ABLE intervention will be associated with a greater number of sedentary breaks over time (ActivPAL).
HYPOTHESIS D: The ABLE intervention will be associated with greater participation over time (Stroke Impact Scale-Participation Subscale).

Study Design & Methods

The study is a single-group quasi-experimental study that will estimate within-group effects of the ABLE intervention on sedentary behavior. All assessment at intervention procedures will be completed by trained research staff (research assistants, interventionists) with supervision provided by the principal investigator.

Screening Procedures:
Participants who verbalize interest in the ABLE study over the telephone will be asked to answer questions over the phone regarding their medical history, age, mobility, daily activities (Sedentary Behavior Questionnaire), and location of residence. These questions will determine initial eligibility.

If, based on telephone screening, participants are eligible and continue to indicate interest, an in-person session will be scheduled to review the full informed consent. This session will be completed in the participant's home. After participants have completed the informed consent process, we will complete standardized clinical assessments (PRIME-MD/MINI, Patient Health Questionnaire-9) to determine eligibility. Participants will complete the PRIME-MD/MINI and Patient Health Questionnaire-9 to screen for mood. These are valid and reliable screening measures (Gilbody et al., 2007; Kroenke, et al., 2002; Spitzer et al., 1999).

Baseline Assessment Procedures:
Participants who provide informed consent, complete screening procedures, and are found to be eligible based on our eligibility criteria will then complete Baseline 1.

BASELINE 1 ASSESSMENTS

Demographic (age, gender, race, ethnicity, education, vocation, pre-stroke residential status and social support), medical (stroke etiology and date of onset, co-morbidities, medications), and rehabilitation history (type and duration) will be gathered via participant interview and medical record review.

Self-Administered Comorbidity Questionnaire is a participant-reported measure of comorbidities. Participants are asked to report on the presence or absence of specific chronic diseases, if they receive treatment for the disease, and if the disease interferes with their daily life activities.

The Stroke Impact Scale-Participation Subscale is a valid and reliable measure of self-reported engagement in community activities. Participants are asked to rate the degree to which they feel restricted in 10 types of participation on a 1 to 5 Likert-type scale. Scores are summed and converted to a 0 to 100 scale where 100 indicates no participation restrictions.

ActivPAL(TM) monitors will be used to assess sedentary behavior and step count over 7 days. The ActivPAL is a small, lightweight monitor that quantifies time spent in sitting, reclined, standing, and stepping. The participant will be provided the "ActivPAL Guide" as a reference guide. We will follow a 24-hour wear protocol in which the participants will wear the device on their thigh for 7 days. During the BASELINE 1 assessment session, the researcher will train the participant on appropriate care and use of the device. The ActivPAL will be waterproofed and fastened to the individual's thigh using a non-latex, gentle adhesive (Tegaderm). Participants will also be asked to record their bedtime and waking time in the "ActivPAL Diary". Sedentary bouts, sedentary breaks, and steps per day will be assessed using the ActivPAL monitor.

BASELINE 2 ASSESSMENTS

BASELINE 2 assessments will be conducted after a 4-week delay. Due to the nature of our 7-day ActivPAL(TM) monitoring, BASELINE 1 occurs during week 1 of the study. The 4-week delay is a time period that we dose-matched to the intervention period, in which there is no intervention and no activity monitoring occurs. This occurs during weeks 2-5 of the study. BASELINE 2 assessments described below will occur during week 6 of the study. Questionnaires will be asked over the telephone, and a researcher will meet the participant at their home to initiate one week of ActivPAL(TM) monitoring as described below. (Estimated participant time: 60 minutes)

ActivPAL(TM) monitors will be used to assess sedentary behavior and step count over 7 days. Participants will be provided with the "ActivPAL Guide" as a reference guide. The ActivPAL is a small, lightweight monitor that quantifies time spent in sitting, reclined, standing, and stepping. We will follow a 24-hour wear protocol in which the participants will wear the device on their thigh for 7 days. During the BASELINE 2 assessment session, the researcher will train the participant on appropriate care and use of the device. The ActivPAL will be waterproofed and fastened to the individual's thigh using a non-latex, gentle adhesive (Tegaderm). Participants will also be asked to record their bedtime and waking time in the "ActivPAL Diary." Sedentary bouts, sedentary breaks, and steps per day will be assessed using the ActivPAL monitor.

The Stroke Impact Scale-Participation Subscale is a valid and reliable measure of self-reported engagement in community activities. Participants are asked to rate the degree to which they feel restricted in 10 types of participation on a 1 to 5 Likert-type scale. Scores are summed and converted to a 0 to 100 scale where 100 indicates no participation restrictions.

ABLE Intervention Procedures

Once participants have completed baseline testing procedures, they will participate in up to 12 intervention sessions. These sessions will be delivered by a rehabilitation professional who has experience in stroke rehabilitation. Each intervention session will last approximately 45 minutes.

The sessions will occur at the participant's home or at a participant-preferred location in the community.

ABLE INTERVENTION: Intervention sessions may be video recorded. During the first intervention session, the participant will describe a typical weekday, Saturday, and Sunday through a semi-structured interview and the "Intervention: Daily Schedule Worksheet." During this process, the therapist will ask the participant to identify portions of the day in which they spend prolonged amounts of time in a seated position. Participants will be oriented to the importance of breaking up sitting time into shortened bouts throughout the day using participation in meaningful daily life activities. Participants will then complete the Activity Card Sort to identify meaningful daily life activities that could be incorporated throughout the day and week to break up prolonged sedentary time. These activities will be documented in the participant's workbook.

Subsequent intervention sessions will focus on scheduling and monitoring participation in daily life activities during times of the day or during activities in which prolonged bouts of sitting time were identified. The sessions will focus around specific time periods that were identified (e.g. every day after lunch, the participant spends 3 hours seated in the recliner) or specific activities in which the participant identifies prolonged sitting time (e.g. while watching television). The participant will select an activity and the therapist will collaborate with the participant to identify strategies for using this activity to break up prolonged seated time. The participant will use a worksheet to schedule the activities and develop a plan for self-monitoring. During the following intervention sessions, the therapist and participant will review the planned schedule and identify successes and barriers to these activities. The participant and therapist will collaboratively generate solutions to identified barriers and a revised plan will be established.

The intervention therapist will document intervention sessions on the "Intervention: Session Notes" document.

After completion of 12 intervention sessions, participants will complete post-intervention assessments and activity monitoring.

Post-Intervention Assessment Procedures

ActivPAL(TM) monitors will be used to assess sedentary behavior and step count over 7 days. Participants will be provided with the "ActivPAL Guide" as a reference guide. The ActivPAL is a small, lightweight monitor that quantifies time spent in sitting, reclined, standing, and stepping. We will follow a 24-hour wear protocol in which the participants will wear the device on their thigh for 7 days. During the BASELINE 2 assessment session, the researcher will train the participant on appropriate care and use of the device. The ActivPAL will be waterproofed and fastened to the individual's thigh using a non-latex, gentle adhesive (Tegaderm). Participants will also be asked to record their bedtime and waking time in the "ActivPAL Diary." Sedentary bouts, sedentary breaks, and steps per day will be assessed using the ActivPAL monitor.

The following questionnaire will be conducted via the telephone:
The Stroke Impact Scale-Participation Subscale is a valid and reliable measure of self-reported

engagement in community activities. Participants are asked to rate the degree to which they feel restricted in 10 types of participation on a 1 to 5 Likert-type scale. Scores are summed and converted to a 0 to 100 scale where 100 indicates no participation restrictions.

Follow-Up Assessment Procedures (8 weeks post-intervention)

ActivPAL(TM) monitors will be used to assess sedentary behavior and step count over 7 days. Participants will be provided with the "ActivPAL Guide" as a reference. The ActivPAL is a small, lightweight monitor that quantifies time spent in sitting, reclined, standing, and stepping. We will follow a 24-hour wear protocol in which the participants will wear the device on their thigh for 7 days. During the BASELINE 1 assessment session, the researcher will train the participant on appropriate care and use of the device. The ActivPAL will be waterproofed and fastened to the individual's thigh using a non-latex, gentle adhesive (Tegaderm). Participants will also be asked to record their bedtime and waking time in the "ActivPAL Diary." Sedentary bouts, sedentary breaks, and steps per day will be assessed using the ActivPAL monitor.

The following questionnaire will be conducted via the telephone:
The Stroke Impact Scale-Participation Subscale is a valid and reliable measure of self-reported engagement in community activities. Participants are asked to rate the degree to which they feel restricted in 10 types of participation on a 1 to 5 Likert-type scale. Scores are summed and converted to a 0 to 100 scale where 100 indicates no participation restrictions.

Eligibility Criteria

Inclusion Criteria:
1) diagnosis of ischemic or hemorrhagic stroke
2) ≥6 months and ≤5 years post-stroke
3) ≥18 years of age
4) ambulatory in the community with or without an assistive device (e.g. walker, cane)
5) self-reported sedentary behavior (≥6 hours/day of sedentary behavior reported using the Sedentary Behavior Questionnaire)
6) reside within 50 miles of Pittsburgh

Exclusion Criteria:
1) severe aphasia (Boston Diagnostic Aphasia Examination score ≤1)
2) currently receiving outpatient or home care rehabilitation services (physical therapy, occupational therapy, or speech therapy)
3) current active cancer treatment
4) medical history of neurodegenerative disorder (i.e. dementia, Parkinson's disease, multiple sclerosis, Lou Gehrig's disease (ALS), glioblastoma, myasthenia gravis)
5) current major depressive disorder, psychiatric condition, substance abuse (assessed via in-person participant interview after signed informed consent, using Patient Health Questionnaire-9, PRIME-MD/MINI)

Statistical Considerations

Primary Outcome Measures:

1. Change in daily sedentary time accumulated in bouts greater than or equal to 30 minutes (Baseline to Week 11), ActivPAL
2. Change in daily number of sedentary breaks (Baseline to Week 11), ActivPAL

Secondary Outcome Measures:

1. Change in daily number of sedentary breaks (Baseline to Week 18), ActivPAL
2. Change in daily sedentary time accumulated in bouts greater than or equal to 30 minutes (Baseline to Week 18), ActivPAL
3. Change in Participation (Baseline to Week 11), Stroke Impact Scale-Participation Subscale
4. Change in Participation (Baseline to Week 18), Stroke Impact Scale-Participation Subscale

PRELIMINARY DATA SCREENING:

We will explore distributions of all descriptive and outcome variables to understand the variance and identify outliers in our data set. We will examine our data set to identify patterns of missing data and descriptive characteristics for whom data were missing.

PRIMARY AND EXPLORATORY OUTCOMES

This study employs a delayed baseline design to allow assessment of baseline stability. We will examine stability on primary and secondary outcomes between baseline 1 (week 1) and baseline 2 (week 6). We will then compute a single mean baseline score for each participant using baseline 1 (week 1) and baseline 2 (week 6).

We will then compute within-person change scores between baseline and post-intervention (week 11) and between baseline and follow-up (week 18). The group's mean change score and standard deviation will be reported.

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Activating Behavior for Lasting Engagement (ABLE) After Stroke

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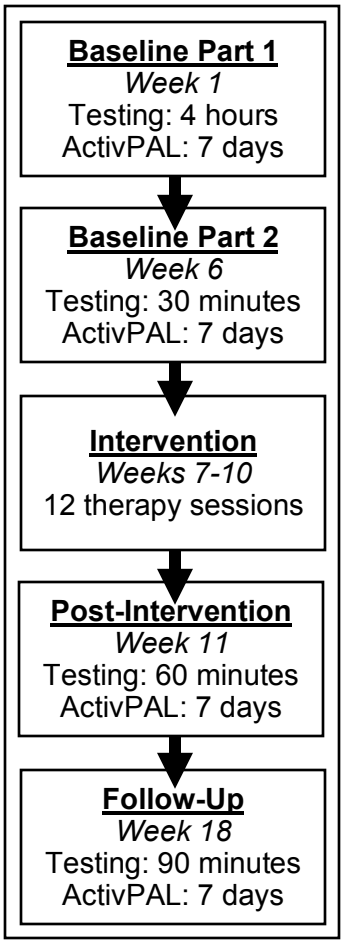
SOURCE OF SUPPORT: No support

Researchers at the University of Pittsburgh are conducting a **research study** to see whether a new rehabilitation intervention, the **A**ctivating **B**ehavior for **L**asting **E**ngagement (ABLE) intervention can help people to be more active in their daily life after stroke. You are being asked to take part in this research study because you have had a stroke at least 6 months ago and less than 5 years ago, and completed our initial screening questions over the telephone. We will ask 25 people to participate in this research study.

Study Screening:

If you decide to take part in this research study, **we will conduct in-person screening, where we will ask you some questions about your current mood, psychiatric history, and current substance abuse**. **These tests will tell us if you are eligible for this study**, and together they will take about 45 minutes.



Study Procedures:

If you are eligible, we will ask you to complete baseline assessments in **two parts**. **Part 1** will occur right away. During Part 1, **we will ask you to complete some tests of your thinking and moving abilities, your arm function, and answer questions about your fatigue, pain, life satisfaction, physical activity, and daily activities.** These tests will take **4 hours total,** and may be **split into 2 sessions.** We may video record portions of this testing.

We will also ask you to **wear an ActivPAL monitor** for **7 days**. An ActivPAL is a small, flat monitor that measures the time you spend sitting, standing, and taking steps throughout the day. The ActivPAL will be waterproofed and fastened to the front of your thigh. You can wear the ActivPAL during all of your daily activities, including water activities. Before we apply the ActivPAL, we will check the sensation on the front of your thigh using a light touch screening test. **During the time that you are wearing the ActivPAL, we will ask you to write down the time that you go to bed and the time that you wake up in the morning in a diary that we will provide.**

Part 2 will occur during week 5. During Part 2, we will ask you to **wear an ActivPAL monitor** for **7 days**, using the same procedure as in Part 1. We will also ask you to **answer questions about your daily activities and your mood**. The questions in Part 2 will take approximately **30 minutes**.

After the tests, a **rehabilitation professional** will **meet with you in person for 12 intervention sessions** in your home. Each session will last for approximately **45 minutes.** During these sessions, the rehabilitation professional will ask you about your daily routines. Your therapist will work with you using the ABLE intervention. The ABLE intervention is a rehabilitation

treatment that involves scheduling meaningful activities throughout your day and problem solving to identify practical strategies to reduce prolonged amounts of time spent sitting. These sessions may be videotaped.

We will ask you to complete some questionnaires about your perspectives on the treatment during the intervention sessions. These questions will take approximately **30 minutes**.

At the end of your last intervention session, we will ask you wear the ActivPAL monitor for **7 days** and to **answer questions about your daily activities and your mood**. This will take approximately **60 minutes.**

We will follow up with you 8 weeks later. At that time, we will ask you to **wear the ActivPAL monitor for 7 days** and to answer questions about your activities, pain, fatigue, outlook on life, and your mood. We will also share some of your ActivPAL data with you and ask you to discuss your activities during times of the week or day when you spent the most time sitting, standing, or stepping. In total, the follow-up activities will take approximately **90 minutes.**

If you were involved in the Adapting Daily Activity Performance Through Strategy Training (ADAPTS) research study through the Occupational Therapy Department at the University of Pittsburgh, we are asking your permission to collect your cognitive test results from that study to use in our analyses for this study. This will prevent you from needing to repeat several of the tests during baseline 1.

As part of this study, we are **requesting your authorization or permission to review your medical records.** We will obtain past, current and future demographic (age, gender, race, ethnicity, education, vocation, pre-stroke residential status, social support), medical (stroke etiology and onset, co-morbidities, medications) and rehabilitation history (type and duration, documented impairments). We will also gather information about the size and location of your stroke from imaging results. This information will be used to help us learn about your stroke and rehabilitation. As part of this research study, some information that we obtain from you may be placed into your medical records. If we identify previously undiagnosed conditions that may benefit from treatment, we will notify you and request permission to notify your primary care physician. In this case, testing results may be placed into your medical record.

Identifiable medical record information will be made available to members of the research team for an indefinite period of time. Your de-identified medical information, as well as information obtained during this research study, may be shared with other researchers in the future. **We will protect your privacy and the confidentiality of your records**, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. This authorization is valid for an indefinite period of time. However, **you can always withdraw your authorization to allow the research team to review your medical records** by contacting the investigators listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research

team. **The possible risks and discomforts of this research study** include the possibility that you may become frustrated, upset, tired during the testing and the treatment sessions. If this happens, you will be allowed to take a break or stop the testing. There is also the risk that information about you may be seen by someone who is not part of the research team. We will make every effort to ensure that your information is protected, so that only authorized persons can see your information. There is a possibility that you may experience a fall or injury during the testing and the treatment sessions. A trained rehabilitation professional will be present during the testing and the treatment sessions. If you do experience a fall or injury, you will receive treatment through UPMC. Finally, there is a possibility that you may experience skin irritation from adhesive used to fasten the ActivPAL monitor to your leg. If skin irritation occurs, you will be able to remove the ActivPAL monitor and we will work with you to identify alternative strategies for fastening the ActivPAL to your leg.

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

You may benefit by participating in the treatment sessions with the rehabilitation professional **but there is no guarantee that this will help you**. We hope to learn whether this intervention is effective to help people return to an active lifestyle after a stroke.

If we learn about any new risks that may cause you to change your mind about continuing to participate, we will let you know.

Neither you, nor your insurance provider, will be charged for any of the procedures performed for the purpose of this research study. You will be charged, in the standard manner, for any procedures performed for your routine medical and rehabilitation care (i.e., doctor or medical visits, treatments, and all other tests and procedures including laboratory tests and imaging that you would normally have as part of your regular medical care).

You will be paid $25 for each completed assessment time-point (Baseline part 1, Baseline part 2, Post-intervention, 8-week follow-up). We will ask some participants to complete only Baseline part 1, Post-intervention, and 8-week follow-up. Thus, you may be paid $75 or $100 for participating in this study. If you do not complete the full study, you will be paid $25 for each completed assessment time point.

Any information about you obtained from this research will be kept as confidential (private) as possible. Research records, including the video, will be stored in a locked file cabinet or in password-protected computer databases, and you will not be identified by name in any publication of the research results unless you sign a separate consent form giving your

permission (release). Our assessment processes include screening for depression, psychiatric conditions. If we identify that you have any of these conditions or that you are at risk for suicide, we will notify you and your primary caregiver. In addition, we may be required to notify your primary care physician. We will also provide you with information regarding resources available to access treatment for these conditions (e.g., crisis network contact information).

In addition to the investigators listed on the first page of this consent form and their research staff, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years and for as long as it may take to complete this research study.

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study, or if you decide to withdraw your consent after you sign this consent form, will have no effect on your current or future relationship with the University of Pittsburgh, UPMC hospital or affiliated health care provider. You may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor. **If you decide not to take part in this research study, you will receive usual rehabilitation care as determined by your clinical team.**

You may withdraw your consent for participation in this research study at any time. Any identifiable research or medical information obtained for this research study prior to the time you formally withdraw your consent may continue to be used and disclosed by investigators for the purposes described above. To formally withdraw your consent for participation in this research study, provide a written and dated notice of this decision to the Principal Investigator of this research study at the address listed on the first page of this form or call the number listed.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

It is important that you understand that participation in the study is above and beyond your usual rehabilitation care. **If you chose not to participate in the study, or chose to withdraw from the study at a later date, you will still receive rehabilitation care**.

You may be removed from the study if it is determined by the research team for any reason that you do not meet criteria for the study or if the investigator believes that further participation in the study would place you at risk for injury (e.g. not following study procedures or demonstrating poor safety judgment).

One of your health care providers may be involved as an investigator in this research study. As both your provider and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another provide who is not associated with this research study. You are not under any obligation to participate in any research study offered by a member of your health care team.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____ _____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

PROXY CONSENT

_____ _____
Participant's Name (Print) Date

The above-named individual is unable to provide direct consent for study participation because

_____

By signing this form I give my consent for him/her to participate in this research study and provide my authorization to share his/her medical records with the research team.

_____ _____
Representative's Name (Print) Representative's Relationship to Participant

_____ _____
Representative's Signature Date

_____ _____
Witness Signature Date

VOLUNTARY ASSENT:

This research has been explained to me, and I agree to participate and to share my medical records with the research team.

_____ _____
Participant's Signature Date

VERIFICATION OF EXPLANATION:

I certify that I have carefully explained the purpose and nature of this research study to the participant in appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.

_____ _____
Investigator's Signature Role in Research Study

_____ _____
Investigator's Printed Name Date

CONSENT FOR CONTINUED PARTICIPATION

I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my authorized representative because of my inability to provide direct consent at the time that this initial consent was requested. I have now recovered to the point where it is felt that I am able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form I agree to participate in this research study.

By signing this form I agree to continue to participate in this research study and provide my authorization to share my medical records with the research team.

_____ _____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date