PROTOCOL TITLE: Life Walker vs. Conventional Rollator and Predicate Mobility Device

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1.0 Objectives

*The **primary objective** of this study is to determine the efficacy of the Life Walker versus a standard rollator walker and predicate assistive device on gait function in adults between 18 to 89 year of age and using a walker with or without back pain*

1.1 Hypothesis's:

Aim 1: Perform in-laboratory training on the Life Walker and testing to compare functional gait outcomes with the Life Walker compared to a conventional rollator and predicate assistive mobility device. *We expect that participants will be able to walk longer and will perform more efficiently on measures of gait function when using the Life Walker.*

Aim 2: Perform in-laboratory testing to compare self-reported pain with the Life Walker compared to a conventional rollator and predicate assistive mobility device. *We expect that participants will report less pain because they will have a more efficient and upright posture when using Life Walker.*

Aim 3: Perform in-laboratory testing to compare measures of quality of life with the Life Walker compared to a conventional rollator and predicate mobility device. *We expect that participants will report better outcomes on quality of life measures because they will experience better self-esteem due to better mobility when using Life Walker.*

2.0 Background

More than 6 Million people in the United States use assistive devices such as canes, crutches, or walker to move independently and to improve their balance. Over 1.5 million of these use walkers (Hamid Bateni) (H. Stephen Kaye). Independent movement is one of the most important factors to uphold quality of life for elderly or people with and patients with gait disorder, muscle weakness and musculoskeletal pain.
Mobility devices, especially rollators are used for improving the endurance, increasing the walking distance and the walking time (Zorica Suica). Due to the bilateral stabilization the base of support allows a bigger tolerance for the body mass center till losing balance. Up to 100% are load on the walker, depending on using which allows a decrease lower limb loading and compensate weakness and decrease fatigue. Wheeled Walker (rollator) need less effort for lifting and moving thereby decrease the energy cost up to 50%. (Ko CY; H. Stephen Kaye) Arm-rest can increase the comfort of the walkers and reduce the weight bearing on lower limbs and on hand and wrists additionally (Ko CY). The Life Walker is an ergonomically designed walker with forearm supports at a position which is meant to relieve pressure on important loading parts of a person's body

leading to better mobility. Thus the study aims at understanding the true utility of the walker.

3.0 Inclusion and Exclusion Criteria

3.1 We will recruit 30 subjects. Most subjects will be recruited through RIC recruitment flyers and from the RIC pain clinic.

Inclusion:

- Individuals using a walker with or without back pain for ambulation.
- Ages from 18 to 89 years old
- Medically stable for therapy

Exclusion

- Patient weight exceeds 300 lbs
- Patient height is below 5'0" or exceeds 6'3"
- Inactive, physically unfit to fit into the device.
- Cognitive deficits or visual impairment that would impair their ability to give informed consent or to follow simple instructions during the experiments.
- MMSE score below 17
- Pregnant women
- Co-morbidity that interferes with the study (e.g. stroke, pace maker placement, severe ischemia cardiac disease, etc.)

4.0 Study-Wide Number of Subjects

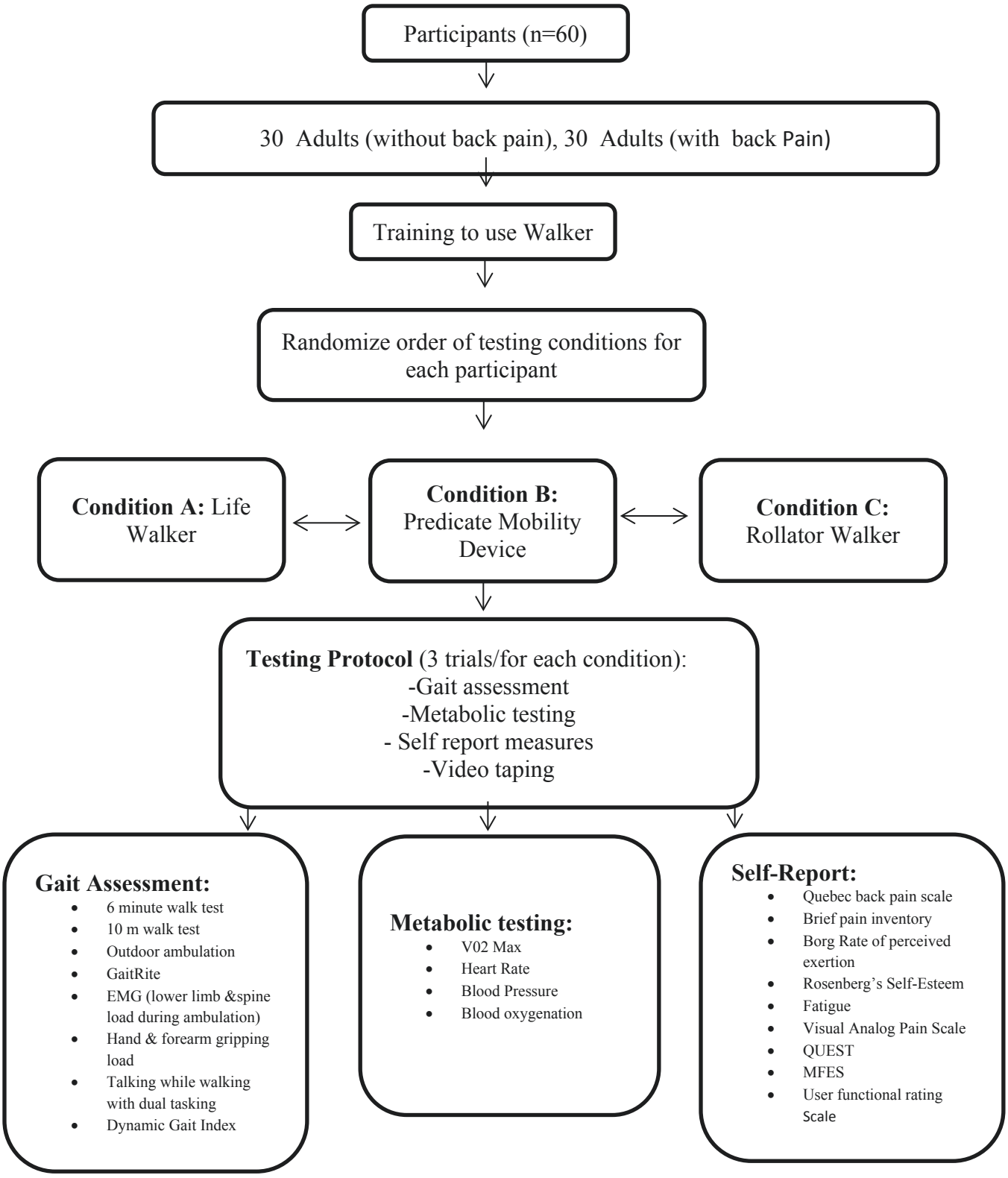
This study will enroll up to 30 older adults who use walkers as a primary mode of transportation, and 30 individuals who use a walker due to low back pain.

5.0 Study-Wide Recruitment Methods

This study will enroll up to 30 eligible subjects. RIC approved flyers will be posted at RIC in-patient, out-patient, day rehabilitation and fitness facilities, as well as pain clinic offices, providing contact information of study recruiters. Authorized research personnel will identify potential subjects from RIC's Cerner Information Systems. Patients will be

considered enrolled into the study after they have signed the Consent Form and HIPAA Authorization for Research.

6.0 Study Timelines: 1-2 days of training



Achievable benchmarks include: (1) recruitment of 30 subjects who use a walked with low back pain and 30 subjects older adults who use a walker; (2) appropriate functional training of the LifeWalker Upright for all of the enrolled participants ; (3) completed clinical, performance outcome and self report measures for all of the of subjects.

8.0 Procedures Involved

Participants will come to the laboratory for a screening and informed consent. Once written consent is obtained, participants will be screen for inclusion eligibility.

Screening/Baseline Procedures

- Informed Consent
- Medical history-Complete medical and surgical history, medications
- Demographics-Age, gender, race, ethnicity
- Review subject eligibility criteria
- Testing sessions will take place over the course of 1-32 days and include the following clinical objective outcome measures, subjective self-report measures and metabolic measures listed.

Overall Sessions:

- Session 1 will include, (i) Consent (ii) Some Self reported measures (baseline) and (iii) Indoor Gait assessment tests with or without metabolics (depending on equipment availability)
- Session 2 will include, (i) Outdoor ambulation, (ii) Indoor gait assessment with or without metabolics (depending on equipment availability), and (iii) Self reported measures
- Session 3 will include, any items that were not completed in session 1 or 2.

- **Life Walker Upright Training Procedures**

8.1 Walker Training procedures

All participants will be trained on the use of the Life Walker and standard Rollater for a time of 15 min. After training all the testing will be begin.

8.2 Walker Testing procedures: *Experimental order of which walker is used first, second and third during the testing will be randomized using a random number generator.*

8.3 Overview: Participants will first complete a series of gait testing. Gait testing will include metabolic testing using the K4B2, load and grip testing using load sensors and upper extremity and spine muscle electromyography (EMG) testing. Participants will also be asked to be videotaped during their training sessions. After all the testing is complete, participants will be asked to complete a set of self-report questionnaires. During each device session, participant heart rate, blood pressure and blood oxygenation will be measured. All of these procedures will be repeated with each device.

8.4 Equipment

- **Cosmed** $K4B^2$ Metabolic unit. Cosmed $K4B^2$ (K4B2 Cosmed, Italy) is a portable gas analysis system that measures oxygen consumption (VO_2) and Carbon-dioxide production (VCO_2) in a breath by breath fashion. $K4B^2$ system consists of a portable unit and battery pack that weight about 2.4 lbs (1100 gm). The portable unit has O_2 and CO_2 analyzers that are bi-directionally connected to a flowmeter and turbine attached to a rubber facemask that is tightly strapped over subject's nose and mouth. $K4B^2$ requires calibration before every testing session due to usage of heated sensors for measurements. Manufacturer's recommend at least 45 minutes warm up time for unit under ambient temperature (ideally at 20°C) before calibration. $K4B^2$ calibration involves verifying flowmeter and concentrations of gases with labeled concentrations. $K4B^2$ acquires heart rate using a telemetric heart rate sensor that is strapped over subject's thorax. The $K4B^2$ and battery pack can be securely placed in slots on a standard harness worn by subject. This harness allows access to buttons on the unit on upper back and minimal interference to activities like walking. Data extraction and processing is carried using $K4B^2$ custom software.
- **Electromyography (EMG):** Muscle activity will be collected from subjects by electrodes placed upon the skin over lower extremity muscles and also on the lower back muscles. This will be collected during the six-minute walk test.
- **Postural measurement (using EMG)**: Muscle activity will be collected from subjects by electrodes placed upon the lower back muscles , upper extremities and lower extremities to measure the posture with each device.
- **Grip and forearm strength load –** Specialty gloves and load cells will be used to measure to amount of load participants are using when using each device on the hands

and also on the forearm. This will be collected during the six-minute walk test.

- **Activity monitors** will be placed on the body or walker to collect body movement data.
- **HR/BP:** Subjects will wear a heart rate monitor during the study and blood pressure will be taken periodically with a standard BP cuff.

8.5 Clinical Testing

- **10 METER TIMED WALK (10mWT):** This test will examine the patient's gait speed. Patients will be directed to walk at a self-selected speed and at their preferred maximum but safe speed. Patients will be positioned 1 meter before the start line and instructed to walk the entire distance and past the end line approximately 1 meter. The distance before and after the course are meant to minimize the effect of acceleration and deceleration. Time will be recorded using a stopwatch and recorded to the one hundredth of a second (ex: 2.15 sec). The test will be recorded 3 times each, with adequate rest in between. The average of the 3 times should be recorded. Participants will complete the 10mWT 6 times with each device: *3 times Self-selected; 3 times Fast-walking*
- **6 MINUTE WALK TEST (6MWT):** The 6 minute walk test is performed as an objective evaluation of functional exercise capacity. The 6minute walk test is easy to administer, well tolerated, and typically reflective of activities of daily living. The test measures the distance that the patient can walk on a flat, hard surface, indoors, in a period of 6 minutes. The walk test is patient self-paced and assesses the level of functional capacity. Patients are allowed to stop and rest during the test, however, the timer does not stop. If the patient is unable to complete the time, the time stopped is noted and reason for stopping prematurely is recorded. We will record the number of stops and stumbles during the test. This test will be administered while wearing a mask to measure oxygen consumption in addition to blood pressure, heart rate and oxygen saturation.

- **TALKS WHILE WALKING TEST (TWWT Dual Task Test) :** The TWWT is used to determine the effects of cognitive attentional demands during walking by

introducing a secondary thinking and talking task, while walking. Participants will perform the following tasks, timed walking up to 50 meters, performing a thinking and talking (numerical and/or vocabulary) task while sitting and a dual task while walking (i.e. performing a thinking and talking task while walking). Participants voice will be recorded when performing all the thinking and talking tasks .

- **GAITRITE DATA CAPTURE:** The GAITRite system automates measuring temporal and spatial gait parameters via an electronic walkway connected to a computer. The GAITRite electronic walkway contains sensor pads encapsulated in a carpet to collect gait information. The system can be laid over any flat surface. The GAITRite electronic walkway for the study shall be a minimum of 14 feet long. The GAITRite data capture was chosen as measurement of the patient's overall gait quality. Patients will be asked to walk at a self-selected speed across the GAITRite electronic walkway. GAITRite. Participants will complete the GAITRite 6 times with each device: *3 times Self-selected; 3 times Fast-walking*
- **OUTDOOR AMBULATION:** All participants will complete a structured outdoor course of straight walkway, ramps, and a standard side walk with curbs as well as a crosswalk. Time and RPE will be measured.
- **DYNAMIC GAIT INDEX (DGI).** The DGI is clinical test that assesses the individual's ability to modify balance while walking with the walkers in the presence of external demands (i.e. demands like, level walking, look up amd down, left and right while walking, stepping over and walking around obstacles and cones).

8.6 Self-Report Questionnaires

- **MODIFIED FALLS EFFICACY SCALE (mFES):** The mFES is self-report questionnaire consisting of 14 items which is designed to measure fear of falling in the elderly. It assesses an individual's perception of balance during activities of daily living by asking "how confident are you that you can do the following activities without falling."

- **MODIFIED FATIGUE IMPACT SCALE (mFIS):** The mFIS is a 21-item short version of perceived impact of fatigue on the subscales of physical, cognitive, and psychosocial functioning.

- **THE QUEBEC USER EVALUATION OF SATISFACTION WITH ASSISTIVE TECHNOLOGY (QUEST)** was designed to measure the level of satisfaction attribute to assistive technologies. It does so using 27 variables which are scored in terms of perceived importance and satisfaction.

- **VISUAL ANALOG PAIN SCALE (VAS):** The Visual Analog Scale Pain Scale is a measure of perceived pain intensity. It consists of a horizontal line that is 10 centimeters long. On either side of the line is a description of pain- to the left the description will read "No pain," and to the right the description will read "worst pain imaginable." The individual is instructed to mark a point on the continuum which represents his/her pain.

- **QUEBEC BACK PAIN DISABILITY Scale:** The back pain scale is a self-report measure that evaluates a patient's functional status related to back pain.

- **BORG RATE OF PERCEIVED EXERTION:** 6-20 item scale that measures perceived exertion during activity.

- **USER FUNCTIONAL RATING SCALE:** Is specifically to assess the user's perception of difficulty in performing the functional tasks when using the different assistive devices. The scale is similar to the patient specific functional scale wherein functional tasks are rated in level of their difficulty from "0" ("inability to perform the task") to "10" ("no difficulty in performing the task.").
- **Brief Pain Inventory:** This scale is a 9-item self-report measure of measure of perceived pain intensity at different body parts in the past 24 hours.
- **Rosenberg's Self-Esteem Scale :**

The Rosenberg Self-Esteem Scale is a 10-item self-report measure of global self-esteem. It consists of 10 statements related to overall feelings of self-worth or self-acceptance. The items are answered on a four-point scale ranging from strongly agree to strongly disagree

9.0 Data Management

9. 1 Subjects' records will be kept completely confidential: Every possible precaution will be taken to protect the privacy interests of subjects. To begin with participation in this is completely voluntary. Trained research personnel will explain the purpose of the study and intended use of subject's personal health information and precautions taken to keep the study information and data confidential. Data will be collected and kept confidential and compliant with HIPPAA requirements. Research data will be de-identified and stored in locked cabinets in the lab with access only to research staff. Electronic data will be de-identified and kept on secure, password protected files and password protected computers of RIC. Only authorized research personnel will have access to the study related data.

9.2 Record Retention: Study documentation will be collected and kept confidential and compliant with HIPPAA requirements. Data will be held for 3 years after the study is completed and published.

10.0 Withdrawal of Subjects*

10.1 Patient voluntarily withdraws

10.2 Patient withdraws consent (termination of treatment and follow-up);

10.4 Patient is unable to comply with protocol requirements

10.5 Patient demonstrates change in medical condition

10.5 Patient experiences adverse event that makes continuation in the protocol unsafe;

10.6 PI judges continuation in the study would not be appropriate;

11.0 Risks to Subjects*

11.1 There is a risk of falling during training and testing. The risk of falling will be reduced by having each participant supervised during training and testing by a trained research professional in all testing procedures and fully trained in device use. During testing and training, the participant will use a gait belt for safety. Each participant will be educated in the safe use of the device and will demonstrate safe use with assistive devices, as necessary. The risk is similar to that during any clinical outpatient physical therapy session.

11.2 There is a risk of muscle soreness due to increased physical activity during training and testing sessions. All subjects will work with trained research staff. Adequate rest will be given and subjects will be monitored by the researchers for verbal or visual signs of fatigue or discomfort.

11.3 There is a risk of skin irritation from using the EMG electrode patches. The adhesive is hypo-allergenic. All subjects will be educated in signs and symptoms of skin irritation and we will remove the patches if irritation occurs.

12.0 Potential Benefits to Subjects

12.1 There will likely be no direct benefit by participating in this research study. The participants might feel the differences between the devices and be better informed on devices that they may have better preferences for.

13.0 Setting

13.1 Procedures will be performed in the clinical laboratory housed in a Rehabilitation inpatient and outpatient hospital.

14.0 Resources Available

14.1 **Staffing:** The RIC houses the Center for Bionic Medicine (CBM) which is an internationally recognized research center focused on the design, control, and evaluation of multi-function technologies for individuals with disabilities. The CBM is a large, fully equipped facility with a research team of more than 35 staff members including physicians, therapists, neuroscientists, engineers, software developers, graduate students, post-doctoral researchers, and administrative staff that facilitates integration of teaching, research, and clinical knowledge.

All training will involve trained research staff, and will occur in compliance with standard clinical training methods. Subject safety will be paramount at all times; harness systems and clinical oversight will be in place when necessary.

14.2 **Facilities:** The PI of this study, Arun Jayaraman, PT, PhD, is Director of the Max Nader Center for Rehabilitation Technologies and Outcomes (MN Center), within CBM at the RIC Hospital. The MN Center has laboratory space of 1000 sq. ft. for clinical evaluation of patients and assessment of ambulation and functional activities. This includes ramps, stairs, parallel bars, and other clinical evaluation equipment. This area is covered by an overhead support system such that a patient can move throughout the room and over obstacles while being safely harnessed in case of a stumble or fall. Adequate dedicated office space is available for private meetings with potential subjects, performing physical evaluations, explaining

the study protocol and obtaining study consent, performing data analysis, and writing manuscripts.

15.0 Recruitment Methods

15.1 **Subjects will be recruited** from the pain clinic at RIC. Furthermore, flyers, or the RIC. Interested participants will be directed to research staff who will inform them of the time commitment required and questioned regarding the inclusion/exclusion criteria. Once subjects have agreed to participate in the study, they will come to RIC for further participation instructions.

15.2 **Subjects will be paid through the Clincard system** if enrolled past the consenting and screening phase of the study. If subjects only come in for one visit they will be paid through petty cash. . Subjects will be compensated up to $100 for completing the study. Subjects will be compensated $50 for the first session and $50 for the second session. However, in the event that protocol needs to be spread across three sessions, subjects will be paid $50 for the first session and $25 for the second and third session.

16.0 Local Number of Subjects

The total number of subjects to be enrolled will be 30. We will enroll 30 participants who use a walker due to back pain and 30 older adults who use a walker.

17.0 Confidentiality

All personal information (names, addresses, email or phone numbers, etc.) gathered for this study that can identify participants will be kept secure to protect their privacy and will never be shared at any time with any person or entity. Data collected during the study and shared with others will reference participants only by an alphanumeric code. The “master list” linking personal information to the alphanumeric code will not be shared, and will be kept by the study PI in a secure location. All personal information linking participants to their data will be destroyed after three years (or according to RIC compliance procedures) following the completion of the study. De-identified information gathered from participants will be used by RIC.

18.0 Provisions to Protect the Privacy Interests of Subjects

Every possible precaution will be taken to protect the privacy interests of subjects. Participation in this study is completely voluntary. Trained research personnel will explain the purpose of the study and intended use of subject’s personal health information and precautions taken to keep the study information and data confidential.

19.0 Compensation for Research-Related Injury

If the research involves more than Minimal Risk to subjects, describe If the subject gets an injury or illness as a result of study, subject is required to promptly notify the PI of the study about the illness or injury. The hospital [Researchers, RIC, Northwestern University and all affiliated clinical sites] will provide the basic immediate clinical care needed, however, any advanced or long-term clinical care will not be provided. Furthermore, any costs related to medical care required because of a bad outcome resulting from participation in this research study will not be compensated by the study PI or associated organization. However, this does not keep subject from seeking to be paid back for care required because of a bad outcome.

20.0 Process to Document Consent in Writing

20.1 Informed consent will take place at RIC's Rehabilitation Technologies and Outcomes Lab in room 1771.

20.2 Trained research personnel will guide the subject through consenting process. Subject will be given detailed explanation of the purpose, time line, commitment, procedures, data handling and privacy and confidentiality of information pertaining to the study.

21.0 Drugs or Devices

21.1 Classification - type of device: Rolling Walker

21.2 Storage and stability: Device is stored at RIC Flagship hospital-Room #1771. The device is accessible only to research staff.

21.3 Availability: Property of the Rehabilitation Technologies and Outcomes Research Lab at RIC.

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