Single-site, Pilot Study Evaluating SimPull as a Primary Means of Lateral Patient Transfer

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Funding Sponsor:	The Patient Company, LLC
Study Product:	SimPull Lateral Transfer Device
Protocol Number: (IRBe)	22-004929

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LIST OF ABBREVIATIONS

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CRF	Case Report Form
DSMB	Data and Safety Monitoring Board
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IDE	Investigational Device Exemption
IRB	Institutional Review Board
PHI	Protected Health Information
PI	Principal Investigator
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect

Study Summary

Title	Single-site, Pilot Study Evaluating SimPull as a Primary Means of Lateral Patient Transfer
Running Title	SimPull A Pilot Study
IRB Protocol Number	*22-004929*
Phase	Pilot
Methodology	*Investigational Device*
Overall Study Duration	Two months
Subject Participation Duration	Two minutes
Objectives	To utilize SimPull as an alternative to current lateral patient transfer methods through the evaluation of SimPull as a feasible means of lateral patient transfer.
Number of Subjects	100
Diagnosis and Main Inclusion Criteria	• Patients requiring lateral transfer for an invasive cardiac procedure to and from gurney to exam table. • Patients requiring lateral transfer for an invasive cardiac procedure to and from exam table to gurney. • Patient does not have compound fractures or cervical fractures present. • Patient does not have skin damage or open wounds to the dorsal cavity. • Patient or legally authorized representative (LAR) must be able/present to sign consent.
Study Device	SimPull Lateral Transfer Device
Duration of Exposure	N/A
Reference therapy	*Note if there is a standard reference therapy against which the study product is being compared, or if the reference is a placebo.*
Statistical Methodology	*A very brief description of the main elements of the statistical methodology to be used in the study. (As few lines as possible).*

1 Introduction

This pilot study will assess the use of the SimPull as an alternative to current lateral patient transfer methods, evaluating if SimPull is feasible as a primary means of lateral patient transfer.

This document is a protocol for a human research study. This study will be carried out in accordance with the procedures described in this protocol, applicable United States government regulations and Mayo Clinic policies and procedures.

1.1 Background

Lateral patient transfer (lateral transfer) is the act of moving a patient from one horizontal surface to another. Lateral transfer is needed for many reasons, including but not limited to admitting patients from a gurney to hospital stretcher, within hospitals for changing units and when going for imaging, surgery, or testing. Lateral transfers are the most common type of patient transfer, Occupational Safety and Health Administration (OSHA) mandates no more than 35 lbs. be lifted by an individual clinician, yet the average patient weight is nearly 200 lbs., meaning an average patient requires six clinicians to be moved per OSHA mandate. Customer discovery sessions found in typical acute care settings it takes 4-minutes on average to recruit each staff member for lateral transfers creating a 22-minute average time when following this OSHA mandate. As 22-minutes is unreasonable to do a transfer, clinicians are currently forced to ignore mandates to stay on schedule, resulting in 12,000 injuries to U.S. clinicians annually. Typically, overexertion injuries to backs, necks, shoulders, wrists, or elbows are not easily remedied; many of these injuries cause lifelong issues. While there are products available to support lateral transfers, these products have the same problem; they require a separate product to be placed underneath the patient to facilitate the transfer. To get patients on these transferrable surfaces an entirely manual process referred to commonly as “log-rolling” must be performed. This manipulation is attributable to up to 50% of injuries related to lateral transfer. Even with these products available, nurses sustain more injuries than any other profession in any other industry and patient transfer, specifically lateral transfer is a major contributor. When nurses sustain these injuries, it makes them vulnerable to further injury, sometimes unable to participate in transfers post-injury. This creates additional burden and increased risk to uninjured staff as they are held accountable to do the same transfers without support from injured staff. Nurses are in high demand and short supply, as the population ages and patient weight increases, supporting a safe work environment for clinicians is critical.

1.2 Investigational Device

SimPull is an automated lateral transfer device that will be used in the catheterization laboratory (cath lab) and electrophysiology laboratory (EP lab) throughout the pilot study. SimPull can complete a lateral transfer in two minutes by one user with zero work force allowing for a removal of the risk of injury while also providing 20-minute reduction in time per transfer. The device is comprised of several important components. The clamp, a unique barbell design utilizes a slip knot to engage to common bed sheets which are readily available under patients. The clamp is attached to an easily cleaned Biothane strap, which feeds into the

motor. The motor generates a pull force allowing up to 500 lbs. of patient weight to be transferred. The motor is housed in a unit, protecting the user, and providing a user interface with clear operating directions. A handheld remote with safety switches is incorporated to ensure staff can guide the patient, the device transfers the patient bearing nearly 100% of the patient's weight. The device utilizes an adjustable feature that allows the height of the device to match the frame of most typical hospital surfaces. The SimPull bumper has two positions, regular, and extended. Once the bumper is in the preferred position, the bumper lock should be engaged and remain locked for the duration of the transfer. The device is the size of a large vacuum on casters that can swivel 360 degrees, making it easy for one person to use and move about floors.

1.3 Clinical Data to Date

There is no available clinical research data to date on the SimPull investigation device.

1.4 Study Rationale and Risk Analysis (Risks to Benefits Ratio)

1.4.1 Study Rationale

The SimPull is a standalone lateral patient transfer device that can be used in environments with limited ceiling access and confined spaces in the acute care setting. The current available products to support lateral transfers, all have the same problem; they require a separate product for the patient to be on top of during transfer. To get patients on these transferrable surfaces is an entirely manual process referred to commonly as "log-rolling" must be performed. This manipulation is attributable to up to 50% of injuries related to lateral transfer. Even with these products available, nurses sustain more injuries than any other profession in any other industry and patient transfer, specifically lateral transfer is a major contributor. When nurses sustain these injuries, it makes them vulnerable to further injury, sometimes unable to participate in transfers post-injury. This creates additional burden and increased risk to uninjured staff as they're held accountable to do the same transfers without support from injured staff.

1.4.2 Anticipated Risks

SimPull is a standalone lateral patient transfer device, that is not yet approved for market, making it an investigational use device. SimPull is meant to be used in many environments, meaning that in interacting with products that are not specifically made to be compatible with SimPull could result in some risk. Specifically, SimPull attaches to sheets under patients, if the sheets are not positioned well, the patient could turn during transfer. SimPull engages to the surfaces that the patient is being transferred to and from, if any surface is not in the braked or locked position there may be risk to the transfer. These risks are mitigated through sensors that prevent transfer if positioning is jeopardized. The last risk is that the device pulls the patient across one surface to another, in doing so there is some friction, though it has been intentionally reduced as much as possible, this friction could result in risk to the patient.

1.4.3 Potential Benefits

SimPull is the only device that allows for lateral transfer without “log-rolling” of the patient. Meaning the patient will experience a much smoother and more comfortable transfer. In addition, patient dignity is preserved as lateral transfer is currently a common patient dissatisfier, with patients stating current methods negatively impact patient dignity. Lastly, a more efficient transfer for all patients means less non-clinical activities for staff resulting in more time spent with patients.

1.5 Anticipated Duration of the Clinical Investigation

The overall duration of the study is estimated at two months to enroll 100 subjects. The subjects will be enrolled in the study only during their cardiac catheterization or electrophysiology procedural visit.

2 Study Objectives

The objectives of proposed study are to:

1. Validate SimPull is feasible as a primary means of lateral patient transfer.
2. Validate SimPull is a safer method of lateral patient transfer than current alternatives objectively through data collection.
3. Validate SimPull increases staff satisfaction of lateral patient transfer.
4. Validate SimPull is a more efficient method of lateral patient transfer than current alternatives objectively through data collection.
5. To identify further product opportunities utilizing the SimPull core technology.

2.1 Primary Objective

The primary objective of this study is to validate the SimPull is a more efficient method of lateral patient transfer than current alternatives.

2.2 Secondary Objective

The secondary objective of this study is to validate the SimPull increases staff satisfaction of lateral patient transfer.

3 Study Design

3.1 General Design

The methods for this pilot study are fundamentally straightforward; preliminary data collection, pilot and data collection, review, and publish. Data of 50 patients using current methods of lateral transfer and 50 patients using the SimPull device for lateral transfer will be

collected. Employees in the cardiac catheterization and electrophysiology procedural areas have been offered the opportunity to complete IRB study member requirements. Employees in the cardiac catheterization and electrophysiology procedural areas will be completing a survey for the 100 lateral transfers. Employees in the cardiac catheterization and electrophysiology procedural areas that have direct patient care responsibilities, completed IRB requirements, have been added as study members on the IRB application, and received hands on education on proper use of the SimPull device, may perform lateral transfers using the SimPull device and complete study surveys. Employees in the cardiac catheterization and electrophysiology procedural areas that have not completed IRB requirements and have not been added as study members on the IRB application, will perform standard of care for lateral transfers and will not complete study surveys. All study members will receive instruction prior to the study on how to complete the survey. The Principal Investigator and Co-Principal Investigator do not have consenting privileges and will not participate in the recruitment or consenting process.

3.2 Primary Study Endpoints

Endpoint 1: Difference between transfer methods in time for transfer.
Endpoint 2: Difference between transfer methods in number of staff involved in transfer.
Endpoint 3: Difference between transfer methods in proportion of transfers following the OSHA mandate of no more than 35 lbs. lifted per staff member (lbs. lifter per staff member calculated as: weight of patient in lbs. divided by number of staff involved in transfer).
Endpoint 4: Paired difference in satisfaction scores (satisfaction with current transfer method and with SimPull) on staff questionnaires.
Endpoint 5: Paired difference in self-rated risk of injury (with current transfer method and with SimPull) on staff questionnaires.

4 Subject Selection, Enrollment and Withdrawal

Patient selection will be based on set inclusion and exclusion criteria of patients scheduled for procedures in the cardiac catherization and electrophysiology procedural area. If the patient meets eligibility requirements, consent will be obtained using a written consent process. The Principal Investigator and Co-Principal Investigator or study members with recorded conflict of interest do not have consenting privileges and will not participate in the recruitment or consenting process. Using REDCap, the study team will enter data based off transfer observations. If patent consents and no IRB approved study member is available to perform the transfer, the patient will be excluded from the study. If the patient meets inclusion criteria, the clinical research coordinator will validate that a study member is present to transfer the patient prior to consent,. Enrollment will begin with the first 50 patients using the current method of transfer-followed by the pre-survey of staff. Staff will then receive training on the SimPull transfer device and the next enrolled 50 patients will be transferred with SimPull; followed by post-survey of staff. Study members are defined as employees (registered nurses and technicians) of Mayo Clinic assigned to the cardiac catheterization and electrophysiology procedural areas.

4.1 Inclusion Criteria

- Patients weighing less than 500 pounds
- Patients requiring lateral transfer for an invasive cardiac procedure to and from gurney to exam table.
- Patients requiring lateral transfer for an invasive cardiac procedure to and from exam table to gurney.
- Patient does not have compound fractures or cervical fractures present.
- Patient does not have skin damage or open wounds to the dorsal cavity.
- Patient or legally authorized representative (LAR) must be able/present to sign consent.

4.2 Exclusion Criteria

- Patients exceeding the SimPull maximum weight of 500 pounds
- Patients who do not require lateral transfer for an invasive cardiac procedure to and from gurney to exam table.
- Patients who do not require lateral transfer for an invasive cardiac procedure to and from exam table to gurney.
- Patient has compound fractures or cervical fractures present.
- Patient has skin damage or open wounds to the dorsal cavity.
- Patient or legally authorized representative (LAR) are unable/present to sign consent.

4.3 Subject Recruitment, Enrollment and Screening

The Research Coordinator screens patients scheduled for procedures in the cardiac catheterization and electrophysiology procedural area in for inclusion and exclusion criteria. Potential subjects who meet inclusion criteria will be consented to participate in the study by the Research Coordinator. Potential subjects are given the opportunity to ask questions prior to consenting. Potential subjects will be enrolled by the Research Coordinator after information is given to the patient in the form of a handout.

4.4 Early Withdrawal of Subjects

4.4.1 When and How to Withdraw Subjects

Subjects may choose to withdraw from the study (withdrawal of consent) at any time prior to use of the SimPull for lateral transfer. Any subject that withdraws their consent will be replaced so data is collected on 50 total subjects per transfer method.

4.4.2 Data Collection and Follow-up for Withdrawn Subjects

No follow-up is necessary for subjects that withdraw their consent.

5 Study Device

5.1 Description

SimPull is comprised of several important components. The clamp, a unique barbell design utilizes a slip knot to engage a common bed sheet. The clamp is attached to a Biothane strap, which feeds into the motor. The motor generates a pull force allowing 500 lbs. of patient weight to be transferred. The motor is housed in a unit, protecting the user, and providing a user interface with clear operating directions. A handheld remote with safety switches is incorporated to ensure staff can guide the patient as necessary with two hands, the device transfers the patient bearing nearly 100% of the patient's weight. The device utilizes an adjustable feature that allows the height of the device to match the frame of any hospital surface. The SimPull bumper has two positions, regular, and extended. Once the bumper is in the preferred position, the bumper lock should be engaged and remain locked for the duration of the transfer. The lock is an orange handle located underneath the bumper. The height of the bumper can be changed using the twist knob located in the back right of the bumper. Slide the bumper to the height needed and use the twist knob to lock the bumper into place. The device is the size of a large vacuum on casters that can swivel 360 degrees, making it easy for one person to use and move about floors.

The SimPull device will be stored in the cardiac catheterization and electrophysiology lab. The device can be cleaned with standard hospital disinfecting wipes.

5.2 Method for Assigning Subjects to Treatment Groups

Patient selection will be based on set inclusion and exclusion criteria of patients scheduled for procedure in the cardiac catherization and electrophysiology procedural area. If the patient meets eligibility requirements, consent will be obtained using a paper consent process.

Patients will not be randomly assigned to treatment group. The first 50 patients (or greater than 50 if there are withdrawals) will have the current method of transfer. The next 50 patients (or greater than 50 if there are withdrawals) will have the SimPull device for transfer.

5.3 Preparation and Administration/Implantation of Investigational Device

The SimPull does not physically engage with the patient. The device utilizes an adjustable bar to facilitate the lateral transfer.

5.4 Subject Compliance Monitoring

The Research Coordinator will track patients through Ptrax.

5.5 Packaging and Labeling

The SimPull will be labeled with:

"CAUTION – Investigational Device. Limited by Federal (or United States) law to investigational use"

5.6 Receiving, Storage, Distribution and Return

The SimPull devices will be delivered to the Dock on the Mayo Clinic Hospital campus by The Patient Company. The devices will be stored in the cardiac catheterization and electrophysiology lab. Upon completion of the pilot study, the devices will be returned to The Patient Company.

5.6.1 Receipt of Investigational Devices

The SimPull devices will be delivered to the Mayo Clinic Hospital campus by The Patient Company. The devices currently reside at the Arizona State University Health Services building. Two SimPull devices will be delivered for the study pilot.

5.6.2 Storage

The SimPull devices will be stored in the cardiac catheterization and electrophysiology lab throughout the pilot study.

5.6.3 Distribution of Study Device

There will be two SimPull devices available for the purpose of the pilot study. Either device can be utilized for lateral patient transfers.

5.6.4 Return or Destruction of Study Device

At routine intervals and at the completion of the study, there will be a reconciliation of devices shipped, devices utilized, and devices remaining. This reconciliation will be logged on the Device Accountability form, signed and dated. Any discrepancies noted will be documented, the sponsor-investigator will be notified and an investigation will be conducted to determine the cause of the discrepancy. The SimPull devices will be returned to The Patient Company. The devices will be placed on the Mayo Clinic Hospital Dock for retrieval by The Patient Company.

5.6.5 Cleaning/Sterilization Procedures

- Cleaning of the SimPull using:
    - Oxivir Tb Wipes
    - Bleach Wipes
    - Observation of device for defects during process

Study Procedures

Schedule of Events

Study Activity
Determine if patient meets eligibility criteria
Consent the patient
Utilize the SimPull for lateral patient transfer
Clean the SimPull device
Complete RedCap Survey

6 Statistical Plan

6.1 Sample Size Determination

Power estimate for feasibility outcomes
A sample size of 50 per transfer type (current method vs. SimPull) is estimated to achieve greater than 99% power to reject the null hypothesis of no difference in time to transfer using a two-sided two-sample equal variance t-test, assuming a mean time for transfer of 7 minutes under the current method and 3 minutes using SimPull, a standard deviation in both groups of 3.5 minutes, and a significance level of 0.5. A sample size of 50 transfers per type is estimated to achieve greater than 99% power to reject the null hypothesis of no difference in number of staff using a two-sided two-sample equal variance t-test, assuming a mean of 5 staff involved in transfer under the current method and 2 staff using SimPull, a standard deviation in both groups of 0.5, and a significance level of 0.5.

6.2 Statistical Methods

Descriptive Statistics

Patient and transfer characteristics will be descriptively summarized by transfer type. Staff questionnaires will be descriptively summarized. The difference between transfer methods in time for transfer and number of staff involved in transfer will be tested using two-sample t-tests. A possible secondary analysis would test differences using a regression model adjusting for differences in patient or transfer characteristics. The difference between transfer methods in proportion of transfers following the OSHA mandate of no more than 35 lbs. lifted per staff member will be tested using a Chi-square or Fisher's exact test. A possible secondary analysis would test differences using a regression model adjusting for differences in patient characteristics. The paired differences in mean staff satisfaction scores and self-rated risk of injury scores will be tested using paired tests.

Primary Hypothesis:

SimPull lateral transfer device is a more efficient and safe method of lateral patient transfer than current methods of lateral transfer.

By recording patient weight and the number of clinicians engaged during manual transfers we can calculate the force needed by each individual. Example: Patient weight: 265 lbs., five clinicians: 53 lbs. per clinician (51% higher than the 35 lb. OSHA mandate). This data collection allows risk assessment of clinician injury during transfer in each location by

establishing weight pulled by clinicians and the number of transfers per day. Using this we can also forecast force required and risk of injury over time. Time to complete in seconds will be recorded for each lateral transfer.

Secondary Hypothesis:

Use of the SimPull device for lateral transfers will increase staff satisfaction and be a preferred method of lateral patient transfer.

Data collected pre and post SimPull implementation

- Employee Satisfaction
- Employee Perception of Injury Risk

Staff/Clinician Participant Survey:

Part 1 of Survey – Pre-Training

1. What is your preferred method for performing lateral patient transfers?
    a. Manual, Assisted, Celling Lift, or Air Mattress
2. Do you feel at risk of injury performing lateral patient transfers?
    a. No Risk, Minimal Risk, Neutral, Some Risk, High Risk
3. How likely do you feel you are to be injured during lateral patient transfer?
    a. Not at all likely, Not Likely, Neutral, Likely, Very Likely
4. What type of injury do you think you would have during lateral transfers?
    a. Open response
5. What preventative measures do you take to avoid injury during lateral transfers?
    a. Open response
6. Are you satisfied with current lateral patient transfer methods?
    a. Yes/No

Part 2 of Survey – Post Training

1. What is your preferred method for performing lateral patient transfers?
    a. Manual, Assisted, Lift, or SimPull
2. Do you feel at risk of injury performing lateral patient transfers using the SimPull?
    a. No Risk, Minimal Risk, Neutral, Some Risk, High Risk
3. How likely do you feel you are to be injured during lateral patient transfer using SimPull?
    a. Not at all likely, Not Likely, Neutral, Likely, Very Likely
4. What type of injury do you think you would have during lateral transfer using SimPull?
    a. Open response
5. What preventative measures do you take to avoid injury during lateral transfers using SimPull?
    a. Open response
6. Are you satisfied with lateral patient transfer using SimPull?
    a. Yes/No

6.3 Subject Population(s) for Analysis

All-treated population that was transferred using the SimPull device in the cardiac catheterization and electrophysiology procedure area.

7 Safety and Adverse Events

All adverse events occurring during the study, including those not meeting the criteria of an Unanticipated Adverse Device Effect (UADE) will be recorded on the appropriate case report form. Records of these events will be maintained and reports submitted to the FDA and IRB according to the regulatory requirements. Expected clinical adverse events and nonsignificant (not serious) clinical adverse events will not be reported. Expected clinical adverse events and anticipated adverse device effects are those listed in Section 1.5.2.

7.1 Definitions

Unanticipated Adverse Device Effect (UADE)
A UADE is any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device if that effect, problem or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or IDE application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Adverse Effect (Event)
Any untoward medical occurrence in a subject involved in clinical study of an investigational device; regardless of the causal relationship of the problem with the device or, if applicable, other study related treatment(s).

Associated with the investigational device: There is a reasonable possibility that the adverse effect may have been caused by the investigational device.

Life-threatening adverse effect: Any adverse effect that places the subject, in the view of either the investigator or the sponsor, at immediate risk of death from the effect **as it occurred**. It does not include a reaction that, had it occurred in a more severe form, might have caused death.

Serious adverse effect: An adverse effect is considered "serious" if, in the view of either the investigator or the sponsor, it results in any of the following outcomes:

- death
- a life-threatening AE
- inpatient hospitalization or prolongation of existing hospitalization
- a persistent or significant disability/incapacity
- a congenital anomaly/birth defect.

Unanticipated adverse effect: Any adverse effect, the nature, specificity, severity, or frequency of which is not consistent with the risk information in the clinical study protocol or elsewhere in the current IDE application.

General Physical Examination Findings
At screening, any clinically significant abnormality should be recorded as a preexisting condition. At the end of the study, any new clinically significant findings/abnormalities that meet the definition of an adverse event must also be recorded and documented as an adverse event.

Hospitalization, Prolonged Hospitalization or Surgery
Any adverse event that results in hospitalization or prolonged hospitalization should be documented and reported as an unanticipated adverse device effect unless specifically instructed otherwise in this protocol. Any condition responsible for surgery should be documented as an adverse event if the condition meets the criteria for an adverse event.

Post-study Adverse Event
All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the local investigator should instruct each subject to report, to the local investigator, any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The local investigator should notify the study regulatory sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study. The sponsor should also be notified if the local investigator should become aware of the development of problems, cancer or of a congenital anomaly in a subsequently conceived offspring of a subject that has participated in this study.

Preexisting Condition
A preexisting condition is one that is present at the start of the study. A preexisting condition should be recorded as an adverse event if the frequency, intensity, or the character of the condition worsens during the study period.

Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO)
Any unanticipated problem or adverse event that meets all of the following three criteria:

- Serious: Serious problems or events that results in significant harm, (which may be physical, psychological, financial, social, economic, or legal) or increased risk for the subject or others (including individuals who are not research subjects). These include: (1) death; (2) life threatening adverse experience; (3) hospitalization - inpatient, new, or prolonged; (4) disability/incapacity - persistent or significant; (5) birth defect/anomaly; (6) breach of confidentiality and (7) other problems, events, or new information (i.e. publications, DSMB reports, interim findings, product labeling change) that in the opinion of the local investigator may adversely affect the rights, safety, or welfare of the subjects or others, or substantially compromise the research data, **AND**

- Unanticipated: (i.e. unexpected) problems or events are those that are not already described as potential risks in the protocol, consent document, not listed in the Investigator's Brochure, or not part of an underlying disease. A problem or event is "unanticipated" when it was unforeseeable at the time of its occurrence. A problem or event is "unanticipated" when it occurs at an increased frequency or at an increased severity than expected, **AND**
- Related: A problem or event is "related" if it is possibly related to the research procedures.

Adverse Event Reporting Period

For this study, the study treatment follow-up period is defined as the post procedure period following the cardiac catheterization or electrophysiology procedure.

7.2 Recording of Adverse Events

At each contact with the subject, the investigator must seek information on adverse events by specific questioning and, as appropriate, by examination. Study subjects will be routinely questioned about adverse effects at study visits. Information on all adverse events should be recorded immediately in the source document, and also in the appropriate adverse event section of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic, laboratory or procedure results should be recorded in the source document.

All adverse events occurring during the study period must be recorded. All observed or volunteered adverse effects (serious or non-serious) and abnormal test findings, regardless of the treatment group if applicable or suspected causal relationship to the investigational device or if applicable other study treatment or diagnostic product(s) will be recorded in the subjects' case history. For all adverse effects sufficient information will be pursued and or obtained as to permit; an adequate determination of the outcome, an assessment of the casual relationship between the adverse effect and the investigational device or, if applicable other study treatment or diagnostic product. The clinical course of each event should be followed until resolution, stabilization, or until it has been ultimately determined that the study treatment or participation is not the probable cause. Serious adverse events that are still ongoing at the end of the study period must be followed up, to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be at least possibly related to the study treatment or study participation should be recorded and reported immediately.

Causality and severity assessment
The sponsor-investigator will promptly review documented adverse effects and abnormal test findings to determine 1) if the abnormal test finding should be classified as an adverse effect; 2) if there is a reasonable possibility that the adverse effect was caused by the investigational device or other study treatments; and 3) if the adverse effect meets the criteria for a serious adverse effect.

If the sponsor-investigator's final determination of causality is "unknown and of questionable relationship to the investigational device or other study treatments," the adverse effect will be classified as associated with the use of the investigational device or other study treatments for reporting purposes. If the sponsor-investigator's final determination of causality is "unknown but not related to the investigational device or other study treatments," this determination and the rationale for the determination will be documented in the respective subject's case history.

7.3 Sponsor-Investigator Reporting of Unanticipated Adverse Device Effects and Unanticipated Problems

When an adverse event has been identified, the study team will take appropriate action necessary to protect the study participant and then complete the Study Adverse Event Worksheet and log. The sponsor-investigator will evaluate the event and determine the necessary follow-up and reporting required.

The sponsor-investigator will promptly review documented Unanticipated Adverse Device Effects and as necessary shall report the results of such evaluation to FDA within 10 working days and Mayo IRB within 5 working days of initial notice of the effect. Thereafter the sponsor-investigator will submit such additional reports concerning the effect as requested.

7.3.1 Sponsor-Investigator Reporting, Notifying Mayo IRB

The sponsor-investigator will report to the Mayo IRB any UPIRTSOs and Non-UPIRTSOs according to the Mayo IRB Policy and Procedures.

7.3.2 Sponsor-Investigator Reporting: Notifying the FDA

The sponsor-investigator will report to the FDA all unanticipated adverse device effects according to the required reporting timelines, formats, and regulations.

The sponsor-investigator will submit a completed FDA Form 3500A to the FDA's Center for Devices and Radiological Health for any observed or reported adverse effect that is determined to be an unanticipated adverse device effect. A copy of this completed form will be provided to the DSMB and all participating sub-investigators.

The completed FDA Form 3500A will be submitted to the FDA as soon as possible and, in no event, later than 10 working days after the sponsor-investigator first receives notice of the adverse effect.

If the results of the sponsor-investigator's follow-up evaluation shows that an adverse effect that was initially determined to not constitute an unanticipated adverse device effect does, in fact, meet the requirements for reporting; the sponsor-investigator will submit a completed

FDA Form 3500A as soon as possible, but in no event later than 10 working days, after the determination was made.

For each submitted FDA Form 3500A, the sponsor-investigator will identify all previously submitted reports that that addressed a similar adverse effect experience and will provide an analysis of the significance of newly reported adverse effect in light of any previous, similar report(s).

Subsequent to the initial submission of a completed FDA Form 3500A, the sponsor-investigator will submit additional information concerning the reported adverse effect as requested by the FDA.

Reporting Process
Unanticipated Adverse Device Effect reports will be submitted on FDA Form 3500A. The contact information for submitting reports is:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Deviations from the investigational plan.

The sponsor-investigator shall notify Mayo IRB (see 21 CFR 56.108(a) (3) and (4)) of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice shall be given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor-investigator is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB notification in accordance with 21 CFR 812.35(a) also is required.

7.4 Medical Monitoring

It is the responsibility of the sponsor-investigator to oversee the safety of the study. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a site data and safety-monitoring plan (see Section 10 Auditing, Monitoring and Inspecting). Medical monitoring will include a regular assessment of the number and type of serious adverse events

8 Data Handling and Record Keeping

8.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (long term survival status that the subject is alive) at the end of their scheduled study period.

8.2 Source Documents

Source data comprise all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial. When applicable, information recorded on the CRF shall match the Source Data recorded on the Source Documents.

8.3 Case Report Forms

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

Data Management

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure clarity of reproduced copies. When

making changes or corrections, cross out the original entry with a single line, and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.

Data Processing

Clinical data (including AEs, concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into a 21 CFR Part 11-compliant password protected web-based electronic data capture (EDC) system with validated electronic records and electronic signatures provided by Mayo Clinic Study Staff. All investigational staff authorized to enter study data will receive training on the EDC system. Training records will be retained by the study team.

The EDC includes internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Any out-of-range values or missing key variables will be flagged at the site in real time during the data entry process. When a query is generated on a particular variable, an exclamation point will be present next to the item in the database enabling the system to track the queries and produce reports of outstanding queries. Queries can also be generated from manual review of the data forms. These queries will be entered into the database and tracked in the same manner as the computer-generated queries. Further cross-checking of the data will be performed, and discrepant observations flagged will be appropriately resolved through a data query system. The data monitoring group will perform internal database quality-control checks, and data audits throughout the course of the trial. Clinical data will be entered directly from the source documents.

Data Security and Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI,

attempts should be made to obtain permission to collect at least vital status (i.e., that the subject is alive) at the end of their scheduled study period.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. Except when required by law, subjects will not be identified by name, personal identification number (e.g., social security number, social insurance number), address, telephone number, or any other direct personal identifier in database records. No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the sponsor.

Authorized representatives of the sponsor, representatives of the IRB or pharmaceutical company supplying study product may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be stored at Mayo Clinic. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by research staff will be secured, password protected and are protected by a firewall.

Data Quality Assurance

QC procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated. Any missing data or data anomalies will be communicated to the site(s) for clarification/resolution.

Following written SOPs, the monitors will verify that the clinical trial is conducted, and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirements (e.g., Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP)).

The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by inspection by local and regulatory authorities.

Data Clarification Process

When a query is generated on a particular variable, an exclamation point will be present next to the item in the database enabling the system to track the queries and produce reports of outstanding queries. Queries can also be generated from manual review of the data forms. These queries will be entered into the database and tracked in the same manner as the computer-generated queries. Further cross-checking of the data will be performed, and discrepant observations flagged will be appropriately resolved through a data query system. The data monitoring group will perform internal database quality-control checks, and data audits throughout the course of the trial. Clinical data will be entered directly from the source documents.

8.4 Records Retention

The sponsor-investigator will maintain records and essential documents related to the conduct of the study. These will include subject case histories and regulatory documents.

The sponsor-investigator will retain the specified records and reports during the study and for the longer of the following;

1. As outlined in the Mayo Clinic Research Policy Manual –"Retention of and Access to Research Data Policy" http://mayocontent.mayo.edu/research-policy/MSS_669717,

   OR

2. A period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

9 Study Monitoring, Auditing, and Inspecting

9.1 Study Monitoring Plan

The investigator will allocate adequate time for such monitoring activities. The Investigator will also ensure that the monitor or other compliance or quality assurance reviewer is given access to all the study-related documents and study related facilities (e.g. pharmacy, diagnostic laboratory, etc.), and has adequate space to conduct the monitoring visit.

9.2 Auditing and Inspecting

The sponsor-investigator will permit study-related monitoring, audits, and inspections by the IRB, the monitor, and government regulatory agencies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The sponsor-investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

Participation as a sponsor-investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable compliance offices.

10 Ethical Considerations

This study is to be conducted according to United States government regulations and Institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted local Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study. The decision of the IRB concerning the conduct of the study will be made in writing to the sponsor-investigator before commencement of this study.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of a subject, using the Approved IRB consent form, must be obtained before that subject undergoes any study procedure. The consent form must be signed and dated by the subject or the subject's legally authorized representative, and the individual obtaining the informed consent.

11 Study Finances

11.1 Funding Source

This study is financed through funding from The Patient Company.

11.2 Conflict of Interest

Any study team member who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor-investigator prior to participation in this study. The Principal Investigator and Co-Principal Investigator (Study member) with recorded conflict of interest do not have consenting privileges and will not participate in the recruitment or consenting process.

11.3 Subject Stipends or Payments

No payments or reimbursements will be distributed in exchange for participation in this study.

12 Publication Plan

The data will be published in one report but as unique locations, allowing analysis of unique benefit or drawback in a specific location, aiming to prove feasibility in each.