Official Title: Calibration and Usability Validation of Patient Monitoring Device for Pressure Injury Prevention and Fall Detection

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Calibration and Usability Validation of Patient Monitoring Device for Pressure Injury Prevention and Fall Detection

Sponsor: Masimo
52 Discovery
Irvine, California 92618

Principal Investigator: [redacted]

Sub-Investigator: [redacted]

Study Device: Masimo Centroid Sensor Monitoring Device
Masimo Radical-7 Pulse CO-Oximeter
Masimo LNCS® Pulse Oximeter Sensors
Masimo Root Patient Monitoring System
Masimo SedLine Brain Function Module and Sensors

Sponsor Protocol Number: RAMS0006

IRB: Baylor Research Institute Institutional Review Board
3310 Live Oak, Suite 501
Dallas, TX 75204

Principal Investigator	**Title**	**Signature**	**Date**
[redacted]	[redacted]		
Sponsor	**Title**	**Signature**	**Date**
Vikram Ramakanth	Director of Clinical Research		

1 INTRODUCTION

This document is a clinical investigational plan for a human research study. The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. By participating in the study, the Investigator agrees to adhere to all stipulations of this protocol, the conditions of IRB approval, federal and local regulatory requirements, 21CFR 812, ISO-14155 and International Conference on Harmonization Good Clinical Practice guidance ICH GCP.

This protocol describes a procedure to collect a subject's position, movement and physiological data using Masimo's Centroid system. The Centroid monitoring system consists of a noninvasive, coin-battery operated, wearable sensor that can be attached to a subject's chest or back and is intended to send the subject's position, movement and activity data to the Root monitoring station via a Bluetooth link. Device and usability data from the Centroid system as well as staff notes about the subject's demographics, vital signs, health condition, and activity will be collected. Additionally, this protocol allows for the placement of Masimo's pulse oximeter system and SedLine brain function monitoring system. The SedLine system will collect EEG data in this patient population. The pulse oximeter system will collect plethysmogram data.

1.1 Background and Rationale

Masimo Corporation is the developer of noninvasive technologies for the measurement and monitoring of physiological variables, such as arterial oxygen saturation (SpO_2), total hemoglobin concentration (SpHb), carboxyhemoglobin concentration (SpCO), methemoglobin concentration (SpMet), acoustic respiration rate monitoring (RAM), and cerebral and regional oximetry (rSO2, O3™). These technologies are noninvasive and have a good patient safety record.

Masimo has developed a new noninvasive sensor named Centroid as a device to aid in preventing hospital-acquired pressure injury or worsening of existing pressure injury by monitoring patient movement, position, and orientation. The sensor is also able to detect falls through the same monitoring features. This type of monitoring may be effective in reducing the debilitating conditions for patients and their extended stays in hospitals, especially in the patient population who are vulnerable to acquire pressure injuries and/or are prone to fall-related injuries.

Each year over 2.5 million individuals in the U.S. develop a pressure injury.[1] Pressure injuries are painful, debilitating and are usually avoidable. Routine repositioning relieves and redistributes pressure over bony prominences. It is a recommended procedure to help mitigate the risks for developing a pressure injury.[2] The Centroid device, through detection of patient position, is a modality to ensure repositioning occurs routinely.

As many as 1 million Americans fall in the hospital every year. Falls result in fractures, lacerations, bleeding and even death. Current practices to prevent falls include assessment of patient risk, scheduled rounding practices and patient specific interventions to prevent falls.[3] The Centroid device is proposed to be an additional technology to assess risk for fall based on patient position and unique modality additive to these current practices.

The Centroid system consists of a wearable, battery-operated, adhesive sensor and a back-end user interface and Root monitor display at the patient bedside as well as a central location (e.g., nursing station). The sensor contains sensing elements [redacted] processor, and a blue-tooth communication chip (BTLE 2.4 GHz). An algorithm [redacted] calculates the patient's relative position and fall as parameters [redacted] The system can generate alarms configured for adverse events related to patient posture, pressure injury risk and fall.

In this study, subject position data and feedback about device usability will be collected. Data collection will also be conducted for Masimo's SedLine brain function monitoring system. Secondary aims are to collect data for the pulse oximeter sensor and SedLine sensor for the purpose of correlating against Centroid sensor's data and further investigation.

1.2 Investigational Devices

The Centroid device is a non-invasive body-worn investigational device that is intended to detect the positional changes and physical movements of a subject. The device mainly consists of [redacted] Bluetooth LE radio, and a coin-cell lithium battery. The Centroid device is a disposable sensor that is capable of adhering to a subject's skin and continuously storing and transmitting positional data wirelessly, to a host instruments/devices to analyze the subject's activities. The sensor's skin-contacting materials are biocompatible and are thermally non-conductive. The device is intended to be used in hospitals, hospital-type facilities, healthcare facilities, and home environments.

Investigational SedLine sensors and patient cables may be used in this study. The SedLine brain function module is non-invasive and uses sensors that adhere to the subject's forehead. The SedLine brain function module uses a sophisticated multivariate algorithm to assess the patient's electroencephalogram (EEG) data from all 4 channels of the SedLine EEG sensor. The SedLine V2 sensor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The SedLine system includes patient cable that connects the sensor and module to the Root multi-function monitoring system, which monitors multiple physiological parameters in healthcare environments.

2 STUDY DEVICES

2.1 Description

Investigational Devices:

Centroid monitoring device

SedLine V2 sensor and V2 patient cable

FDA-cleared Devices:

SedLine brain function module

Root monitor*

Radical-7 Pulse CO-Oximeter

LNCS SpO_2 sensors

*NOTE: during the validation stage of the study, the FDA-cleared Root monitor will be updated with Centroid software. The Root monitor at this time will be considered an investigational device, although no new patient risks will be introduced by the addition of the Centroid software.

2.2 Device Accountability

2.2.1 Receipt of Study Device

Masimo may ship or hand-carry devices and sensors to the investigative sites. Upon receipt of the study device supplies, an inventory must be performed and the Equipment Shipment Check Form ([redacted]) and the device accountability log will be completed for each device and signed by the receiver. It is important that the designated study staff counts and verifies that the shipment contains all the items noted in the shipment inventory. Any damaged or unusable study devices in a given shipment will be documented in the study files. The investigator must notify the study sponsor of any damaged or unusable study devices that were supplied to the investigator's site.

2.2.2 Use of Study Device

Use of devices and sensors will be documented on case report forms (CRF) for each subject. Any unused devices must be returned to the Sponsor at the end of the study or before product expiration date.

2.2.3 Return or Destruction of Study Device

At the completion of the study, there will be a final reconciliation of study devices. This reconciliation will be logged on the device accountability log. Any discrepancies noted will be investigated, resolved, and documented prior to return or

destruction of unused study devices. Devices destroyed on site will only be upon written instruction from the Sponsor and will be documented in the study files.

2.2.4 Device Deficiencies

Device deficiencies are defined as the inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Record all device deficiencies on the case report form and report to the Sponsor.

2.3 Risk/Benefits

Benefits: There will be no direct benefits to the enrolled subjects. Future benefits to subjects include effective pressure injury prevention (i.e., reduction in their occurrence and/or severity) and detection of hospital falls.

Centroid device risks: As with all wearable sensors, the Centroid sensor has a risk of thermal burn as there is a coin battery in the sensor. The coin battery used in the Centroid device is widely used in other commercially available medical devices for wearable monitoring applications. Masimo's design includes safeguards against thermal burn, and this risk is believed to be low. Sensors will be attached with a medical-grade, biocompatible adhesive. Marks may appear on the skin beneath the sensor due to adhesion for a long period (from several hours to days). The risk is believed to be low. The sensor transmits that data, after on-sensor processing, via a radio link to the host device.

SEDLine V2 sensor and V2 patient cable risks: All patient-contact materials, including the adhesive used in the design of the Masimo sensors, have been subjected to biocompatibility tests per ISO 10993-1 and results demonstrate that the materials are non-toxic, non-irritating, and non-sensitizing. The sensors have been evaluated for mechanical and electrical safety and the risks have been determined to be minimal. The modifications to the sensor are specifically designed so as not to introduce any new risks to the subject.

Pulse oximeter risks: The Radical-7 pulse CO-oximeter device and LNCS® pulse oximeter sensors used in this study are FDA-cleared.

Root patient monitoring system risks: The Masimo Root Monitoring System and SedLine brain function module used during this study are FDA-cleared devices.

3 STUDY OBJECTIVES

The primary aim of this study is to collect data for *calibration* and *usability validation* of the new Centroid monitoring system which Masimo has developed for monitoring a patient's position and movement to prevent pressure injury and detecting falls in the hospital. This protocol describes data collection from patient volunteers during their routine hospital stay lasting usually for more than one day. During the calibration phase, positional data will be collected for the purpose of evaluating the Centroid design and technology. [redacted]

Secondary aims are to collect data for the pulse oximeter sensor and SedLine sensor for the purpose of correlating against Centroid sensor's data and further investigation.

4 STUDY DESIGN

4.1 General Design

This is a prospective clinical study of Masimo's Centroid sensor in patients to collect movement, position, and other physiological data from a sensor placed on the subject's chest or back. LNCS pulse oximeter sensors will be placed on subjects according to their tolerance of the sensors. SedLine sensors may be placed on subjects while they are asleep.

4.2 Study Endpoint

For the data collection and calibration phase of the study, there are no study endpoints. For the centroid usability validation phase of the study, user feedback will be collected from a questionnaire and analyzed [redacted]

5 CLINICAL SITE

Baylor University Medical Center
Webb Roberts Hospital
3500 Gaston Avenue
Dallas, TX 75246

6 SUBJECT SELECTION AND WITHDRAWAL

6.1 Population Base

Subjects will be at least 18 years of age. Subjects will be recruited from Baylor University Medical Center. A total enrollment of at least 60 unique subjects is targeted.

6.2 Inclusion Criteria

- At least 18 years of age
- ICU patient
- Primarily bedbound subjects
- Able to be monitored for a minimum of approximately 8 hours

6.3 Exclusion Criteria

- Pregnancy
- Prisoner status
- Pressure injury stage 2, 3, or ungroupable
- Has a pacemaker or internal defibrillator
- Has a history of complications with a similar study
- Has any medical condition which in the judgment of the Investigator, renders them inappropriate for participation in this study

6.4 Study Timelines

Each individual subject may participate in this study from approximately 8 hours to 16 hours. Data collection may start only after the informed consent has been signed by the participant. The subject will be considered to have completed the study after at least 8 hours of Centroid data have been collected. The study is expected to be completed within 12 months of initiation.

6.5 Subject Recruitment and Screening

Following identification of a potential subject, the patient will be approached by the principal investigator or a designated research staff member, who will explain the purpose and procedures of the study. If the patient expresses interest in participating in the study, they will be asked to read the written Informed Consent Form in English or Spanish depending on the patient's language preference.

All items of the Informed Consent will be explained in a way that is easily understandable, for either English or Spanish speaking subjects. The patient will be given adequate time to read through the Informed Consent, and they will be given adequate time and privacy to consider the decision of whether or not to sign the Informed Consent Form. Once all of the patient's questions have been answered and the Informed Consent Form signed, the patient is now adequately consented.

Now the patient will be enrolled as a study subject, at which time the subject will be assigned a study identification number or enrollment number.

All subjects will have their medical history reviewed at the time of screening by either the PI or the study staff who is delegated for this task. Subjects will be evaluated based on the inclusion and exclusion criteria to determine eligibility to be enrolled into the study. If a subject is deemed ineligible after screening, the subject will be withdrawn from the study.

Information regarding the subject's demographic (including, but not limited to age, weight, race, ethnicity, etc.), preexisting allergies, skin abnormalities, and other preexisting diseases/conditions that may be relevant to the study will be recorded within a paper-based Case Report Form (CRF).

HIPAA

The pre-screening of patients will require the investigators to access personal health information to identify prospective subjects without HIPAA authorization prior to obtaining written informed consent for the study. Informed consent and HIPAA authorization will be obtained during recruitment and screening procedures as described in previous sections of this clinical investigation plan; however, pre-screening process would require a waiver of HIPAA authorization, as the research study could not be practicably carried out without this implied waiver of consent. The participants' rights and welfare will not be adversely affected by waiving consent. Patients' protected health information (PHI) will not be inappropriately reused or disclosed to any other person or entity. To further safeguard all protected health information, the data collected during the study will not be labeled with any personal identifying information, or with a code that this research team can link to personal identifying information. The data will not be stored with any protected health information identifiers.

6.6 Early Withdrawal of Subjects

6.6.1 Withdrawal of Individual Subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences or loss of benefits to which they are otherwise entitled. Subjects may be withdrawn from the study prior to expected completion for reasons such as safety concerns, failure to adhere to protocol requirements, subject consent withdrawal, etc.

Any data collected until the time of subject withdrawal may be included in the final data analysis. Information on the subject's withdrawal should be documented in the case report form and should include clear documentation of the reason for withdrawal to the Sponsor.

6.6.2 Follow-up for subjects withdrawn from study

None. There are no long term effects anticipated from participating in this study.

6.6.3 Replacement of individual subjects after withdrawal

In case a subject leaves the study prematurely, another volunteer may be recruited.

7 STUDY PROCEDURES

7.1 Subject's demographic information, vital signs, [redacted] and all specified parameters will be noted in the subject's Case Report Form.

7.2 Centroid sensor placement

[redacted] The sensors will then be turned on. [redacted] The duration of the study for each subject will be at least 8 hours each day of monitoring up to 16 hours. Sensors may be replaced after 8 hours of use on a subject. If the

sensor is removed for a procedure, surgery, x-ray, or other reasons, the sensor may be placed back on the subject depending on the subject's comfort or at the PI's discretion.

[redacted] Study staff will also record the Root's displayed patient position.

7.3 LNCS Pulse oximeter sensor placement

The LNCS pulse oximeter sensor may be placed on the subject's finger. The data collection will be initiated on the Root monitor. The sensor may be removed at any time, depending on the subject's tolerance of the sensor.

7.4 SedLine sensor placement

[redacted] The SedLine sensor will be applied to the subject's forehead and data collection will be initiated on the Root monitor. The sensor may be removed at any time, depending on the subject's tolerance of the sensor.

7.5 The study will be terminated at the discretion of the PI if any significant adverse event is observed.

7.6 At the conclusion of the study, devices and data recording will be stopped and all sensors will be removed from the subject.

7.7 The skin will be inspected for any signs of redness or irritation.

8 SAMPLE SIZE AND STATISTICAL CONSIDERATIONS

8.1 Calibration and Validation stage

The calibration stage will continue until a sufficient number of cases have been obtained with quality data (e.g. no data drop-outs). Initial data sets may be considered training sets and may not be used for device calibration. Documentation will be included in the study records of when the calibration stage has concluded and when the validation stage commenced.

8.2 Usability validation

In the validation stage, since this is a usability validation only, there is no statistical justification needed for the sample size. The study will enroll at least 30 subjects for this stage.

9 SAFETY AND ADVERSE EVENTS

9.1 Definitions

The definitions for adverse event, adverse device effect, serious adverse event, serious adverse device effect, and unanticipated adverse device effect are provided below (ISO 14155:2011, 21 CFR 812.3(s)).

- Adverse Event (AE): an adverse event is any untoward medical occurrence in a subject which need not be related to the device under investigation.
- Adverse Device Effect (ADE): an adverse device effect is any untoward or unintended response to a medical device which may result from insufficiencies in the instructions for use or deployment of the device, or from use error.
- Serious Adverse Event (SAE): a serious adverse event is an adverse event that results in death, inpatient hospitalization, severe or permanent disability, a life threatening illness or injury, fetal distress, fetal death, a congenital abnormality, a birth defect, or medical or surgical intervention to prevent permanent impairment to body or structure.
- Serious Adverse Device Effect (SADE): a serious adverse device effect is an adverse device effect that results in death, inpatient hospitalization, severe or permanent disability or is life threatening.
- Unanticipated Adverse Device Effect (UADE): any serious adverse effect on health or safety or any life threatening problem or death cause by or associated with, a device, if the effect, problem, or death was not previously identified in

nature, severity or degree of incidence in the investigational plan, or application (including a supplementary plan or application) or any other unanticipated serious problem associated with a device that related to the rights, safety or welfare of subjects. Refer to the Device Risk Analysis and Risk Assessment section for details on anticipated adverse device effects.

9.2 Anticipated Adverse Events:

Sensor may cause slight, temporary redness, which should fade away shortly after sensor removal.

Sensor may cause thermal burn; however, the design includes safeguards and this risk is believed to be minimal. There may be mild allergic reaction to sensor material and adhesives.

9.3 Adverse Event Reporting:

- All Adverse Events, both Anticipated and Unanticipated, must be recorded in the within the CRF and in the Adverse Event Report Form.
- All Adverse Events must be promptly reported to the Sponsor.
- All Unanticipated Adverse Device Effects will be also reported to both the Sponsor and the IRB.
- Both Serious Adverse Events and Unanticipated Adverse Device Effects must be reported to the Sponsor within 48 hours. All other Adverse Events should be reported to the Sponsor within 5 business days.
- All Serious Adverse Events will be also reported to the IRB per IRB reporting requirements. These reports may include, but will not be limited to: date of onset; brief description of the events; their treatment; whether they resulted in death, inpatient hospitalization, severe or permanent disability or were life threatening; their relationship to the study device; and resolution.

9.4 Deviations from the study protocol

Deviations from the protocol must receive both Sponsor and the investigator's IRB approval before they are initiated with the exception that under emergency circumstances, deviations from the CIP to protect the rights, safety and well-being of human subjects may proceed without prior approval of the sponsor or the EC. Any protocol deviations initiated without Sponsor and the investigator's IRB approval that may affect the scientific soundness of the study, or affect the rights, safety, or welfare of study subjects, must be documented and reported to the Sponsor and to the investigator's IRB as soon as a possible, but no later than 5 working days of the protocol deviation. If protocol deviations continue to occur frequently at a study site, a corrective and preventive action (CAPA) may be opened by the Sponsor.

9.5 Withdrawal of IRB approval

An investigator shall report to the sponsor a withdrawal of approval by the investigator's reviewing IRB as soon as a possible, but no later than 5 working days of the IRB notification of withdrawal of approval.

10 VULNERABLE POPULATIONS

10.1 Definition

10.1.1 Vulnerable populations are defined as disadvantaged sub-segment of the community requiring utmost care, special considerations and protections in research. This study will recruit subjects from the following: economically disadvantaged or unemployed, educationally disadvantaged, and limited English skills and/or Non-US citizens.

10.2 Protection of vulnerable subjects

- There is no compensation provided for economically disadvantaged subjects to eliminate possibility of undue influence due to financial incentive.
- Educationally disadvantaged subjects will be provided ample time to ask questions and comprehend information.

- Subjects with limited English skills and/or Non-US Citizens will be provided translated documents in native language, staff/independent interpreter, and have ample time to ask questions and understand information.
- Medical care will be provided to these subjects after the clinical investigation has been completed if they are injured as a direct result of participating in this research study. The cost of treatment for any research related injury will be covered by Masimo.

10.3 Responsible Parties

- The IRB will review research with vulnerable populations and evaluate consent, level of risk, coercion, and the reason for choosing this particular subject population. The IRB will be responsible for determining what practices will include continuing review for compliance while monitoring these studies.
- The Investigator holds the ultimate responsibility for protecting the rights, safety, and welfare of research subjects by ensuring that all regulations and proper documentation of consent is handled in a compliant and timely manner.

11 DATA MANAGEMENT

11.1 Confidentiality of Records

Information about the patients will be kept confidential. The data will be stored on a password protected database on a secure server, accessible only to the Investigators. Study data that will be released to Masimo and other regulatory authorities will be de-identified and will only pertain to study data collection, demographics, finger location of the sensor, and the recordings from the pulse oximeter.

11.2 Source Documents

Source data is 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, recorded data from automated instruments, and copies or transcriptions certified after verification as being accurate and complete. For this study, the case report forms may also be used as source worksheets.

11.3 Case Report Forms

The Site shall capture study data in the CRFs for each subject enrolled. The CRFs will be completed and initial and dated by the PI or delegated personnel. This also applies to those subjects who fail to complete the study. If a subject withdraws from the study, the reason must be noted on the CRF. Case report forms are to be completed on an ongoing basis. CRF entries and corrections will only be performed by study site staff, authorized by the investigator. Entries and corrections to the CRF will be made following Good Documentation Practices.

The CRF will include the following information, including but not limited to: inclusion/exclusion criteria, whether patient consent obtained before start of study, demographic information, device readings, and if occurrence of any adverse event, protocol deviation, and device deficiencies, etc. The CRFs will be signed by the PI to attest that the data is complete and accurate and forward a copy to Masimo.

CRF entries will be verified by study monitor and any errors or inconsistencies will be queried to the site on an ongoing basis. Any changes will be made directly on the paper CRFs and re-verified. Query resolution will be assessed and confirmed by study monitor during site visit. The monitor or study manager will collect original completed and signed CRFs at the end of the study. A copy of the completed and signed CRFs will remain on site

11.4 Data Transfer and Storage

Training on CRF completion will be provided to study personnel prior to data collection. Original CRFs will be stored in a secure location at site. Original CRFs will be scanned and sent to sponsor. [redacted]

[redacted]device data will be downloaded from the devices and transferred to Masimo using secure file transfer protocols.

CRFs will be checked for accuracy and completeness of data. If there are inconsistent or missing data points, a data query list will be generated and submitted to the PI or designee, who shall both follow GDP practices for data correction by striking through the old entry, adding in new entry with initial and date, and resend to Masimo the corrected CRF. Once all queries have been resolved, Masimo engineers are notified that data is ready for analysis. To ensure data integrity, Masimo engineers will only have read access to study data, therefore are unable to unintentionally tamper with the original data files.

11.5 Record Retention

All study information, including but not limited to study correspondence, study logs, device accountability records, consent forms, subject records, and copies of CRFs should be maintained in the Investigator site files.

Study records shall be retained during the study and for a minimum of two years after date of study closure or date when records are not required to support 510(k) clearance. The Institution's own retention policies and regulations may apply in addition to the minimal requirement.

The Sponsor is responsible for verifying study data, retaining records, analyzing data, and authoring study reports.

12 MONITORING PLAN

12.1 As the Sponsor of this clinical investigation, Masimo Corporation is required by 21 CFR, Part 812, of the Food and Drug Administration regulations to monitor and oversee the progress of the investigation. The monitor(s) assigned by Masimo Corporation to this task will be a direct employee from the Clinical Research department trained on departmental SOPs on conduct and monitoring of Sponsored studies.

12.2 In accordance with good clinical practices guidelines, there will be at least three scheduled monitoring visits to ensure overall regulatory compliance of the study:

[redacted]

12.3 The Investigator shall allow access to all source documents needed to verify the entries in the CRFs and other GCP-related documents (IRB approvals, IRB correspondences, and ICFs) provided that subject confidentiality is maintained in agreement with HIPAA regulations.

12.4 It will be the monitor's responsibility to inspect the CRFs at regular intervals throughout the study, to verify the adherence to the CIP and the completeness, consistency and accuracy of the data being entered on them.

12.5 During each visit, the monitor will also verify presence of informed consent, adherence to the inclusion/exclusion criteria, and documentation of SAEs/SADEs and protocol deviations/violations, and check CRF against medical records as necessary.

12.6 After each visit, the monitor will provide a monitoring follow-up letter to the investigator within 4 weeks of visit completion. The follow-up will detail findings and open action items observed during the visit. It is the responsibility of the Principal Investigator and Study Coordinator(s) to respond to the findings of the monitoring report, and complete any open action items as soon as possible but no later than 30 days of receiving the monitoring report. Any open action items not completed within the time allowed may be sufficient grounds for study site

suspension or termination; it will be up to the sponsor to determine whether any incomplete action items are sufficient grounds for suspension or termination. See Section 13 for details on suspension and termination.

12.7 Depending on the quality of the data and/or changes to factors affecting patient safety, additional monitoring visits may be necessary according at the sponsor's discretion.

13 ADMINISTRATIVE ASPECTS

13.1 Protection of Human Subjects

Per 21 CRF 50, written consent must be obtained from each subject or from their legal guardian prior to any study procedures in accordance with applicable federal, state, and study site regulations. The Investigator must keep a copy of the signed consent form in each subject's record and provide a copy to the subject as well. The Investigator shall not allow a subject to participate in a study or sign consent prior to IRB approval.

Prior to the start of data collection or subject enrollment, the Investigator must provide documentation of IRB approval of the study protocol and a copy of the approved informed consent form (21 CFR 50).

All subjects will be monitored closely throughout the study. The following measures will be taken to ensure the privacy of subjects:

- A code (unique identification) number for each subject will be kept on file.
- Only their correspondence identification number will identify subjects.
- Access to the documents and data will only be made to the Investigators and study staff in the study.
- The confidentiality of these documents will be protected to the extent provided by the law.

13.2 Institutional Review Boards

The Sponsor and/or Investigator must submit the protocol to the appropriate IRB and obtain a copy of the written and dated approval letter.

The approval letter should state the name of the documents reviewed, date of review, date of approval, and reference the study name (protocol title, study number, and version).

The informed consent used by the Investigator must be reviewed and approved by the Sponsor prior to submission to the IRB. The Investigator cannot enroll subjects until a copy of the approved informed consent is obtained from the IRB.

Any amendments to the protocol or informed consent should be submitted to the IRB for review and approval per 21 CFR 56. The IRB should be notified of any changes that may affect conduct of the study or pose safety risks to the subjects.

13.3 Confidentiality

All data collected will be kept confidential and de-identified. It can only be accessed by researchers and will be used for research purposes only.

13.4 Protocol Amendments

Any changes made to the clinical investigational plan/study protocol will be documented by way of an amendment. Before submitting protocol amendment to the IRB for approval, the protocol amendment must be agreed upon and signed by both the Investigator and the Sponsor. The Investigator shall not make any changes to the protocol without Sponsor approval and documented approval from the IRB. Both PI and Sponsor will retain the IRB approval letter and approved protocol as confirmation that the protocol amendment was approved.

13.5 Suspension or Termination of Study Site

The Sponsor can suspend or prematurely terminate the PI's and study site's participation in the study, particularly if Sponsor finds serious non-compliance by the PI or site, and if such non-compliance was not resolved in a timely manner. The Sponsor

will document the decision to suspend or terminate the investigation in writing. A suspended study site cannot enroll new subjects.

If the Sponsor determine that the study site's compliance to GCP and federal regulations to be inadequate at any point during the study, and Sponsor move to suspend or terminate the study site, the Sponsor will provide notification in writing to the principal investigator and IRB as necessary. The study site is eligible for reinstatement upon correction of any findings and any open action items prior to the suspension, and provides a written guarantee that the same non-compliance will not reoccur in the future. Site can only resume patient enrollment upon receiving written notification of reinstatement from the Sponsor and/or IRB.

13.6 Termination of Clinical Investigation/Study due to UADE

The clinical investigation may be terminated if Sponsor determines that an unanticipated adverse device effect presents an unreasonable risk to the subjects. Termination shall occur not later than 5 working days after the Sponsor makes this determination, and not later than 15 working days after the Sponsor first received notice of the effect.

The Sponsor may resume the terminated clinical investigation with prior IRB approval if the device is non-significant risk.

14 AGREEMENT BETWEEN INVESTIGATOR AND SPONSOR REGARDING RESPONSIBILITIES FOR GOOD CLINICAL PRACTICE

International Conference of Harmonization (ICH) E6 Good Clinical Practice guidance is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

It specifies general requirements intended to:

- Protect the rights, safety and well-being of human subjects,
- Ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results,
- Assist Sponsors, monitors, Investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

The Principal Investigator of the clinical investigation shall:

- Obtain and maintain IRB approval of the study.
- Ensure all subjects are consented prior to enrollment, per FDA Code of Federal Regulations titled 21 CFR 50.
- Conduct the clinical investigation in accordance with the protocol, all applicable laws and federal regulations, and conditions or restrictions implemented by the governing IRB.
- Ensure only appropriately trained personnel will be involved in clinical investigation.
- Maintain study records mentioned in the CIP.
- Maintain logs for study team delegation, site visit/monitoring, equipment disposition, study team training, subject recruitment and enrollment.
- Evaluate all adverse events and adverse device effects and determining whether the study is safe to continue.
- Allow the Sponsor to conduct periodic monitoring of study activities to ensure GCP compliance.
- Not promote device prior to clearance by FDA for commercial distribution, except for academic purposes and scientific presentations.

The Sponsor shall ensure existence and record of all necessary compliance documents, and will conduct monitoring visits to ensure appropriate conduct of the study.

[redacted]

[redacted]

16 REFERENCES

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2. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Ulcer Injury Alliance. Prevention and treatment of pressure ulcers: Quick reference guide. Emily Haesler (Ed.). Cambridge Media: Perth, Australia; 2014
3. Ganz, DA, Huang, C, Saliba D, et al. Preventing falls in hospitals: A toolkit for improving quality of care. (Prepared by RAND corporation, Boston University School of Public Health, and ECRI Institute under Contract No. HHSA2902010000171 TO#1). Rockville, MD: Agency for Healthcare Research and Quality; January 2013. AHRQ Publication No. 13-0015-EF.