**Title:** *Rahm Neo-Guardian Sensor Pilot Study – Non-invasive monitoring trial*

*Principal Investigator: Dr. Helen H. Hu*

**Investigational Agents** *(if applicable)***:**

|  |  |
| --- | --- |
| Device Name: | Neo-Guardian(™) |
| IND Number: | N/A |
| Sponsor: | Rahm SD Inc. |
| Manufacturer: | Rahm SD Inc. |

# TABLE OF CONTENTS

[TABLE OF CONTENTS 5](#_heading=h.1fob9te)

[STATEMENT OF COMPLIANCE 9](#_heading=h.3znysh7)

[1](#_heading=h.2et92p0) PROTOCOL SUMMARY 10

[1.1](#_heading=h.tyjcwt) Synopsis 10

[1.2](#_heading=h.3dy6vkm) Schema 10

[1.3](#_heading=h.1t3h5sf) Schedule of Activities (SOA) 14

[2](#_heading=h.4d34og8) INTRODUCTION 16

[2.1](#_heading=h.2s8eyo1) Study Rationale 16

[2.2](#_heading=h.17dp8vu) Background 16

[2.3](#_heading=h.26in1rg) Risk/Benefit Assessment 16

[2.3.1](#_heading=h.lnxbz9) Known Potential Risks 16

[2.3.2](#_heading=h.35nkun2) Known Potential Benefits 16

[2.3.3](#_heading=h.1ksv4uv) Assessment of Potential Risks and Benefits 17

[3](#_heading=h.44sinio) OBJECTIVES AND ENDPOINTS 17

[4](#_heading=h.2jxsxqh) STUDY DESIGN 19

[4.1](#_heading=h.z337ya) Overall Design 19

[4.2](#_heading=h.3j2qqm3) Scientific Rationale for Study Design 20

[4.3](#_heading=h.3oy7u29) Justification for Dose 20

[5](#_heading=h.1y810tw) STUDY POPULATION 20

[5.1](#_heading=h.4i7ojhp) Inclusion Criteria 21

[5.2](#_heading=h.2xcytpi) Exclusion Criteria 22

[5.3](#_heading=h.3whwml4) Inclusion of Vulnerable Participants 23

[5.3.1](#_heading=h.2bn6wsx) Participation of NIH Staff or family members of study team members 24

[5.4](#_heading=h.qsh70q) Inclusion of Pregnant Women, fetuses or neonates 24

[5.5](#_heading=h.3as4poj) Lifestyle Considerations 24

[5.6](#_heading=h.1pxezwc) Screen Failures 25

[5.7](#_heading=h.49x2ik5) Strategies for Recruitment and Retention 25

[5.7.1](#_heading=h.3o7alnk) Costs 26

[5.7.2](#_heading=h.23ckvvd) Compensation 26

[6](#_heading=h.1hmsyys) STUDY INTERVENTION 26

[6.1](#_heading=h.41mghml) Study Interventions(s) Administration 27

[6.1.1](#_heading=h.2grqrue) Study Intervention Description 27

[6.1.2](#_heading=h.243i4a2) Dosing and Administration 28

[6.2](#_heading=h.3fwokq0) Preparation/Handling/Storage/Accountability 31

[6.2.1](#_heading=h.1v1yuxt) Acquisition and Accountability 31

[6.2.2](#_heading=h.4f1mdlm) Formulation, Appearance, Packaging, and Labeling 31

[6.2.3](#_heading=h.2u6wntf) Product Storage and Stability 31

[6.2.4](#_heading=h.19c6y18) Preparation 31

[6.3](#_heading=h.3tbugp1) Measures to Minimize Bias: Randomization and Blinding 31

[6.4](#_heading=h.28h4qwu) Study Intervention Compliance 32

[6.5](#_heading=h.nmf14n) Concomitant Therapy 32

[7](#_heading=h.37m2jsg) STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL 33

[7.1](#_heading=h.1mrcu09) Discontinuation of Study Intervention 33

[7.2](#_heading=h.46r0co2) Participant Discontinuation/Withdrawal from the Study 34

[7.3](#_heading=h.111kx3o) Lost to Follow-up 35

[8](#_heading=h.3l18frh) STUDY ASSESSMENTS AND PROCEDURES 35

[8.1](#_heading=h.206ipza) Screening Procedures 35

[8.1.1](#_heading=h.4k668n3) Screening activities performed prior to obtaining informed consent 36

[8.1.2](#_heading=h.2zbgiuw) Screening activities performed after a consent for screening has been signed 36

[8.2](#_heading=h.1egqt2p) Study Evaluations & Procedures 36

[8.2.1](#_heading=h.3ygebqi) Biospecimen Evaluations 38

[8.2.2](#_heading=h.2dlolyb) Correlative Studies for Research/Pharmacokinetic Studies 38

[8.2.3](#_heading=h.sqyw64) Samples for Genetic/Genomic Analysis 39

[8.3](#_heading=h.2r0uhxc) Safety and Other Assessments 42

[8.4](#_heading=h.1664s55) Adverse Events and Serious Adverse Events 44

[8.4.1](#_heading=h.3q5sasy) Definition of Adverse Event 44

[8.4.2](#_heading=h.kgcv8k) Definition of Serious Adverse Events (SAE) 45

[8.4.3](#_heading=h.1jlao46) Classification of an Adverse Event 45

[8.4.4](#_heading=h.43ky6rz) Time Period and Frequency for Event Assessment and Follow-Up 47

[8.4.5](#_heading=h.2iq8gzs) Adverse Event Reporting 48

[8.4.6](#_heading=h.xvir7l) Serious Adverse Event Reporting 49

[8.4.7](#_heading=h.3hv69ve) NIH Intramural IRB Reporting of IND Safety Reports 51

[8.4.8](#_heading=h.1x0gk37) Events of Special Interest 51

[8.4.9](#_heading=h.4h042r0) Reporting of Pregnancy 51

[8.5](#_heading=h.2w5ecyt) Unanticipated Problems 51

[8.5.1](#_heading=h.1baon6m) Definition of Unanticipated Problems (UP) 51

[8.5.2](#_heading=h.3vac5uf) Unanticipated Problem Reporting 52

[9](#_heading=h.2afmg28) STATISTICAL CONSIDERATIONS 52

[9.1](#_heading=h.pkwqa1) Statistical Hypothesis 52

[9.2](#_heading=h.39kk8xu) Sample Size Determination 52

[9.3](#_heading=h.1opuj5n) Populations for Analyses 53

[9.3.1](#_heading=h.48pi1tg) Evaluable for toxicity 53

[9.3.2](#_heading=h.2nusc19) Evaluable for objective response 53

[9.3.3](#_heading=h.1302m92) Evaluable Non-Target Disease Response 53

[9.4](#_heading=h.3mzq4wv) Statistical Analyses 54

[9.4.1](#_heading=h.2250f4o) General Approach 54

[9.4.2](#_heading=h.haapch) Analysis of the Primary Endpoints 54

[9.4.3](#_heading=h.319y80a) Analysis of the Secondary Endpoint(s) 55

[9.4.4](#_heading=h.1gf8i83) Safety Analyses 55

[9.4.5](#_heading=h.40ew0vw) Baseline Descriptive Statistics 56

[9.4.6](#_heading=h.2fk6b3p) Planned Interim Analyses 56

[9.4.7](#_heading=h.upglbi) Sub-Group Analyses 56

[9.4.8](#_heading=h.3ep43zb) Tabulation of individual Participant Data 57

[9.4.9](#_heading=h.1tuee74) Exploratory Analyses 57

[10](#_heading=h.4du1wux) REGULATORY AND OPERATIONAL CONSIDERATIONS 57

[10.1](#_heading=h.2szc72q) Informed Consent Process 57

[10.1.1](#_heading=h.184mhaj) Consent/Assent Procedures and Documentation 57

[10.1.2](#_heading=h.j8sehv) Consent for minors when they reach the age of majority 60

[10.1.3](#_heading=h.279ka65) Considerations for Consent of NIH staff, or family members of study team members 61

[10.1.4](#_heading=h.338fx5o) Consent of Participants who are, or become, decisionally impaired 61

[10.2](#_heading=h.meukdy) Study Discontinuation and Closure 62

[10.3](#_heading=h.36ei31r) Confidentiality and Privacy 63

[10.4](#_heading=h.1idq7dh) Future use of Stored Specimens and Data 64

[10.5](#_heading=h.1ljsd9k) Safety Oversight 65

[10.6](#_heading=h.45jfvxd) Clinical Monitoring 66

[10.7](#_heading=h.2koq656) Quality Assurance and Quality Control 67

[10.8](#_heading=h.zu0gcz) Data Handling and Record Keeping 68

[10.8.1](#_heading=h.3jtnz0s) Data Collection and Management Responsibilities 69

[10.8.2](#_heading=h.4iylrwe) Study Records Retention 70

[10.9](#_heading=h.2y3w247) Protocol Deviations and Non-Compliance 70

[10.9.1](#_heading=h.3x8tuzt) NIH Definition of Protocol Deviation 71

[10.10](#_heading=h.2ce457m) Human Data Sharing, including Genomic Data Sharing, and Publication 71

[10.10.1](#_heading=h.rjefff) NIH Data Management and Sharing Policy and NIH Genomic Data Sharing Policy Compliance 71

[10.10.2](#_heading=h.3bj1y38) NIH Public Access Policy Compliance 72

[10.11](#_heading=h.42ddq1a) Collaborative Agreements 72

[10.11.1](#_heading=h.2hio093) Agreement Type 72

[10.12](#_heading=h.4anzqyu) Conflict of Interest Policy 72

[11](#_heading=h.2pta16n) ABBREVIATIONS 73

[12](#_heading=h.14ykbeg) REFERENCES 74

# STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

* + United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; an IRB determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

# PROTOCOL SUMMARY

## Synopsis

|  |  |
| --- | --- |
| **Title:** | Rahm Neo-Guardian(™) Sensor Development – Non-Contact Vital Sign Monitor Pilot Study |
| **Study Description:** | The goal of this study is to obtain data on the usability and effectiveness of the Rahm Neo-Guardian sensor in neonatal participants, specifically, to collect heart rate, respiratory rate, and skin temperature data. |
| **Objectives:** | The primary objective is to collect heart rate, respiratory rate, and skin temperature data using the Rahm Neo-Guardian non-invasive, non-contact monitoring system and compare with current standard ECG and pulse oximetry via skin contact electrodes and temperature via skin contact thermistor. |
| **Endpoints:** | This is a pilot trial with descriptive statistics to power a future study. Heart rate, respiratory rate, and skin temperature data will be collected with the Rahm Neo-Guardian Sensor and compared to traditional measurement systems, and are expected to be within 95% of those traditional values. |
| **Study Population:** | 40 term and preterm, clinically stable infants of varying gestational ages in the neonatal intensive care unit (NICU). The study population is to be divided categorically by gestational age, with approximately 15 infants in each category outlined below.   * Normal term infants 37 0/7 to 41 6/7 weeks (>2,500 g) * Late Preterm infants 34 0/7 to 36 6/7 weeks (>2500 g) * Low birth weight (LBW) 28 0/7 to 33 6/7 weeks (1500 g - 2,500 g) |
| **Phase:** | Pilot |
| **Description of Sites/Facilities Enrolling Participants:** | University of Florida Health Shands Hospital Well Baby Nursery and NICU. |
| **Description of Study Intervention:** | The participants will be monitored with the Neo-Guardian sensor to collect heart rate, respiratory rate, and temperature from various device positions. They will simultaneously have the same vital signs collected with approved conventional collection devices. |
| **Study Duration:** | The study duration will be six months. |
| **Participant Duration:** | In this pilot study, infants will be monitored for 1 hour per day. |
|  |  |
|  |  |
|  |  |

## Schema

Prior to

Total N: Screen potential participants by inclusion and exclusion criteria; Obtain informed consent; Then obtain demographics and enter into database to document.

Enrollment

Install Neo-Guardian device to IV pole at specified height and distance from subject.

Connect subject to a cardiorespiratory monitoring device for heart rate and respiratory rate, take temperature and record.

Administer initial study intervention.

Measurement 1

**Final Assessments**

**Heart Rate, Respiratory Rate and Temperature measurements collected with Rahm Sensor will be compared to traditional measurements**

## Schedule of Activities (SOA)

| **Procedures** | Day 1 | 15 minutes | 1 hour | Post study |
| --- | --- | --- | --- | --- |
| Pre-screen questions for inclusion | X | X | - | - |
| Informed consent | X | X | - | - |
| Demographics | X | X | - | - |
| Administer study intervention | X | - | X | - |
| Vital signs | X | - | X | - |
| Review collected Data | - | - | - | X |

# INTRODUCTION

## Study Rationale

Rahm Sensor Development, Inc. (Rahm) has developed a non-contact vital signs monitor and has tested the system extensively on animal participants. The Company is currently selling this system into the veterinarian marketplace through a license to Zomedica, Inc., under the brand name VETGuardian(™). Other uses for this platform have been identified including non-contact pediatric, and neonatal monitoring. Rahm is currently developing a system for this market, the Neo-Guardian(™).The goal of this study is to obtain pilot data on Neo-Guardian(™), its accuracy, usability and effectiveness in volunteer human infant participants. The study will collect heart rate, respiratory rate, and temperature using the Rahm device and compare with current standard connected vital sign monitoring methods including skin temperature sensors, pulse oximetry, and ECG electrodes. Our goal is to collect data across both preterm and term newborns as a first step towards commercialization and FDA clearance of the device for newborn human use. A similar system, the Xandar Kardian XK300, received FDA clearance for use with adult humans in US hospitals, nursing homes, and residential homes.

## Background

Rahm Sensor Development, LLC ([www.rahmsd.com](http://www.rahmsd.com)) is developing the Neo-Guardian utilizing Frequency-Modulated Continuous-Wave (FMCW) radar and AI algorithms for accurate vital sign detection. It can monitor heart rate, respiratory rate, and body temperature non-invasively from a distance of up to 5-6 feet, thanks to its advanced radar technology. This non-contact approach, supported by thermal imaging and LiDAR, ensures precision even in environments with movement and noise. This device has not previously been tested on humans, but has had extensive testing and use with animals (Vet Guardian). See APPENDIX A; APPENDIX B.

The device is designed with user interaction in mind, offering an intuitive and comfortable experience. Its non-intrusive patient interface aligns with our commitment to patient-centric design. Accompanying the device is a specialized software application compliant with healthcare privacy standards like HIPAA. This application allows healthcare professionals to have comprehensive control over the device's functionalities, including real-time data visualization and protocol customization.

Currently, our focus is on assessing the usability and performance of the Neo-Guardian, ensuring seamless integration with patient and healthcare provider needs. This phase involves testing of the device's sensor accuracy, data processing capabilities, and overall user experience, emphasizing the device's potential in various healthcare settings including mental health, assisted living, neonatal and pediatric care, and infectious disease management.

## Risk/Benefit Assessment

### Known Potential Risks

**Risk Category:** Minimal

**Medical Risk:** Clinicians taking care of an enrolled participant may inadvertently act based on unvalidated vital sign data from the study device. In order to avoid this, the study device screen will be covered and clinicians will be educated to use standard of care monitoring only when making clinical decisions.

**Electronic Emissions Risk:** The primary risk is exposure to radio waves from the Rahm sensor suite.

**Device Contact Risk:** The device will be securely mounted on the IV support structure. Even if the devices were to somehow fall from its mounting, it would not contact the patient.

**Data Security Risks:** Although this is a minimal risk study with no identifiable patient data collected, the following potential data security risks exist:

* **Unauthorized access to study data stored on local devices**, including laptops and sensor hardware, which may compromise research integrity.
* **Loss or theft of physical devices** (e.g., laptops, USB drives) where data are temporarily stored during collection.
* **Accidental exposure of study files during transport, transfer, or reporting.**
* **Improper disposal or long-term storage of research data**, which could result in non-compliance with institutional or regulatory requirements.

**Protection against risks:** In the case that the study causes discomfort at any time, the PARENT or LEGAL GUARDIAN will be given the option to discontinue the study. This is not expected.

### Assessment and Mitigation of Potential Risks

**Electronic Emissions Risk**: The potential risks are minimal, no more than what is encountered in routine hospitalization. Thermal and optical imaging in the Rahm device are completely passive and pose no risk to the patient. The Frequency-Modulated Continuous-Wave (FMCW) radar system emits 5.8 GHz microwave radiation to accurately map micro-motions of the participant’s body. This is non-ionizing radiation in the EMF range of RF similar to radiation received from many other devices in the home like a cell phone or WiFi router. The power levels emitted by the Rahm sensor are between 2 and 30 times less than a WiFi router.

RF exposure from the 5.8Mhz radar signal has been tested at F2 Laboratories. The FCC safety limit is 1 mW/cm^2 and the device under test produced 0.00002 mW/cm^2 for the radar and 0.0223 mW/cm^2 for the WIFI component of the system. Even if you scale the Radar for the size of the patient (which is usually done with SAR, but not Power Density used here), this provides a significant safety margin.

**Device Contact Risk**: Participants will be distanced from the device and at no time in contact with any instrumentation.

**Data Security Risk:** To reduce or eliminate these risks, the following safeguards will be implemented:

1. **Data De-identification**:

* All collected data will be linked to participants using a unique study ID with no personally identifying information (PII).
* No PHI (Protected Health Information) will be collected or stored.

1. **Device Security and Access Control**:

* All study data will be stored on password-protected, institution-issued laptops.
* Laptops are not connected to public networks during data collection to reduce exposure.
* Only authorized and trained study personnel will have access to these devices.

1. **Secure Storage**:

* When not in use, study laptops and the Neo-Guardian device will be stored in a locked office at Convergent Engineering or the UF NICU site.
* Data will not be transmitted over email or external networks.

1. **No Cloud Storage or Third-Party Hosting:**

* Data will remain local and will not be uploaded to any external servers or cloud environments during this pilot study.

1. **Audit Trails**:

* All data access and modifications will be logged in manual records and verified by the PI during quality control checks.

1. **Data Disposal & Retention**:

* Upon study completion, data will be securely archived for at least 2 years or as required by institutional policy.
* Devices will be wiped clean or reassigned per sponsor-approved SOPs.

1. **Training & Oversight**:

* All study personnel receive training on data privacy and secure handling procedures as part of study initiation.
* Any breach or suspected breach will be reported to the PI and IRB immediately.

### Known Potential Benefits

**For Participants**: There are no potential benefits to study participants.

**From the Application of this Technology:** Successful deployment of a non-contact vital sign monitor would eliminate the need for additional probes and wires and outweighs risks that are already incurred in everyday life. Limiting contact with an at-risk newborn would reduce the risk of infection and, perhaps, improve comfort. For clinicians and other observers, fewer wires reduces tripping hazards, data entry errors, and the accidental disconnection of essential sensors.

# OBJECTIVES AND ENDPOINTS

| OBJECTIVES | ENDPOINTS | JUSTIFICATION FOR ENDPOINTS |
| --- | --- | --- |
| Primary |  |  |
| *Study and Compare Heart rate, respiratory rate and temperature collected with the Neo-Guardian and traditional methods.* | *Heart rate, respiratory rate and temperature collected with the Rahm Sensor simultaneously with traditional methods will be compared and evaluated with an expectation of less than 5%% average absolute error* | *To prove the Rahm Sensor non contact measurements are within 95% of existing contact methods* |

# STUDY DESIGN

## Overall Design

* This is a single center observational study.
* Hypothesis: Non-Contact measurements of HR, RR, and temperature will be within 95% of traditional vital monitoring measurements
* Type of trial: Non inferiority pilot study
* Methods used to minimize bias: see section 5.7
* Number of study groups/arms: 3
* Name of study intervention: Rahm Neo-Guardian System

## Scientific Rationale for Study Design

This is a pilot study. The non-contact intervention is being used to evaluate HR, RR, and temperature in comparison to standard-of-care contact methods of collection. The non-inferiority study is being used to show comparison between the two methods to be within 95%.

# STUDY POPULATION

## Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

* Admitted to the NICU at UF Health/Shands and anticipated to be admitted for at least 24 hours
* Primary English speaking
* Clinically stable at the time of enrollment (defined as off invasive mechanical ventilation and not requiring major medical or surgical interventions in the prior 48 hours)
* Meet one of the following gestational age and birth weight categories:  
  + **Term infants**: 37 0/7 to 41 6/7 weeks GA and birth weight >2,500 g
  + **Late preterm infants**: 34 0/7 to 36 6/7 weeks GA and birth weight >2,500 g
  + **Low birth weight (LBW) preterm infants**: 28 0/7 to 33 6/7 weeks GA and birth weight 1,500–2,500 g
* Parent(s) or legal guardian(s) available and capable of providing informed consent

## Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

* Major congenital anomalies
* Current or recent (within 48 hours) clinical instability which may impact blood flow and accuracy of doppler measurements (e.g., requiring inotropes, invasive ventilation, shock)
* Anticipated discharge within 24 hours

* Infants who do not meet the weight criteria as defined in the inclusion criteria: >28 0/7 to 33 6/7 weeks GA and > birth weight 1,500–2,500 g.
* Infants with severe skin conditions that might interfere with accuracy of measurements.

* Presence of implanted medical devices (eg. pacemakers, ventricular assist devices) that may interfere with measurements
* Infants whose parents or guardians are unable to provide informed consent for participation in this study

## Inclusion of Vulnerable Participants

* This study will include neonates admitted to the neonatal intensive care unit (NICU) who are considered vulnerable participants. Due to the fragile nature of this population, the study will aim to minimize any potential risk, discomfort, or deviation from standard of care in the use of non-invasive doppler technology to monitor vital signs. The risk is considered minimal, meaning no greater than risks encountered with routine neonatal care and will be designed to minimize disruption and discomfort for the neonate. Informed consent will be obtained from the parents or legal guardians of all participants through a clear and thorough process. Participants may optto withdraw from the study at any time without impact on their medical care. Exclusion criteria are established to avoid enrolling neonates with particularly high risk medical conditions or circumstances that would pose undue risk or affect accuracy of data collection that would impact study validity.

### Participation of Study Staff or Family Members

Children of study team members may be enrolled as participants. Neither participation nor refusal to participate as a participant in the research will have an effect, either beneficial or adverse, on the participant’s care.

Every effort will be made to protect participant information, but such information may be available in records and may be available to authorized users outside of the study team in both an identifiable and unidentifiable manner.

## Inclusion of Pregnant Women, fetuses or neonates

* As outlined in section 5.3

## Lifestyle Considerations

* N/A

## Screen Failures

Screen failures are defined as participants who consent to participate in the clinical trial but are not subsequently assigned to the study intervention or entered in the study. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants, to meet the Consolidated Standards of Reporting Trials (CONSORT) publishing requirements and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, eligibility criteria, and any serious adverse event (SAE).

## Strategies for Recruitment and Retention

* **Number of participants requested:** 40
* **Number of sites:** 1
* **Gender of participants:** Both male and female, roughly equally distributed. The study will be advertisedthrough word of mouth, email, and recruitment flyers posted within the UF Shands NICU and outpatient prenatal clinic sites.
* **Racial and ethnic origin:** Current estimates of the racial and ethnic composition of our local community and region suggest that our sample will consist of approximately 20% African- American and 8-10% Hispanic people. These estimates are based on the current population of the area and are approximately matched in prior recruiting efforts in our community using similar methodologies.
* **Vulnerable participants:** All neonatal patients are considered vulnerable participants..
* **Recruitment:**

The study team will conduct **daily screening of the NICU census** to identify eligible infants using electronic medical record (EMR) review and consultation with the clinical care team. A trained research coordinator will assess gestational age and birth weight eligibility and will evaluate clinical stability based on chart review and clinician input.

Eligible infants will be categorized into one of the three gestational age groups, with the goal of enrolling approximately equal numbers across categories.

To maintain equitable enrollment, a **quota system** will be implemented to monitor enrollment progress and adjust recruitment efforts in real time. Once a gestational age category is filled, further enrollment in that subgroup may be paused or deprioritized to ensure balanced representation across all predefined strata.

### Costs

There are no costs to participants in this study.

### Compensation

Participants will be paid with a $50 gift card (visa/mastercard/American Express)

No injuries are expected as this is a minimal risk study, however if the participant is injured as a direct result of participating in this trial, the sponsor, Rahm SD Inc, will cover any charges that are not covered by an insurance policy or the government providing the injury is not due to an underlying illness or condition and was not caused by the participant or a third party.

# STUDY INTERVENTION

## Study Interventions(s) Administration

### Study Intervention Description

The Rahm sensor will be used to collect heart rate, respiratory rate and temperature by a non-contact method during the study.

* Device Name: NEO-Guardian System
* Pilot study, pre-FDA clearance
* The NEO-Guardian will be used as a non-contact device to collect heart rate, respiratory rate and temperature
* Exposure time: 1 hour
* This device has not been approved or cleared for use with humans. It has been shown to be effective and safe in animals and is based on the same technology that has been cleared in other devices. See section 8.3; APPENDIX A; APPENDIX B.
* As described in the protocol, Pursuant to 21 CFR § 812.2 concerning Investigational Device Exemptions, part (b) a Nonsignificant risk device. Under the requirements in this subsection, no FDA approval is necessary for clinical study to commence. The device under study in this protocol is considered a Nonsignificant Risk Device because under 21 CFR § 812.3(m) :
  + It is not intended as an implant nor presents potential for serious risk to the health, safety, or welfare of a participant;
  + It is not purported for use in supporting or sustaining human life;
  + It is not substantially important in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health
  + And it does not otherwise present a potential for serious risk to the health, safety and welfare of the participant. See section 8.3.

## Preparation/Handling/Storage/Accountability

The device will be used and handled only at the Shands Hospital.

### Acquisition and Accountability

The device will be delivered to the Study Coordinator by Rahm SD Inc. It will stay at Shands Hospital for the duration of the study. It will only be used by the trained PI and study staff.

### Formulation, Appearance, Packaging, and Labeling

The device will not be distributed to study participants so no formal packaging or labeling is needed.

### Product Storage and Stability

The device will be stored at Shands Hospital and will not leave the temperature controlled facility.

### Preparation

No preparation is needed for the device as it is not being distributed to participants.

## Measures to Minimize Bias: Randomization and Blinding

N/A

## Study Intervention Compliance

The NEO-Guardian will only be used on site and will not be sent with participants. Study staff will be trained and in control of the device for the duration of the study. The system will automatically track all vital signs. The “standard” contact methods of collection for heart rate, respiratory rate and temperature will be collected and recorded only by study staff.

## Concomitant Therapy

N/A

# STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

## Discontinuation of Study Intervention

Discontinuation from NEO-Guardian evaluation does not mean discontinuation from the study. No other actions will need to be taken on part of the participant. If a clinically significant finding is identified after enrollment (including, but not limited to changes from baseline), the investigator or qualified designee will determine if any change in participant management is needed. Any new clinically relevant finding, causing harm to the patient, will be reported as an adverse event (AE).

No other data will be collected at the time of study intervention discontinuation.

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue or withdraw a participant from the study for the following reasons:

* Completion of study intervention
* If any clinical adverse event (AE),or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
* Investigator discretion

## Participant Discontinuation/Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue or withdraw a participant from the study for the following reasons:

* Significant study intervention non-compliance
* If the participant meets an exclusion criterion (not previously recognized or that develops with ongoing care in the NICU) that precludes further study participation
* Screen Failure

The reason for participant discontinuation or withdrawal from the study will be recorded on the NEO-Guardian Case Report Form (CRF). Participants who sign the informed consent form but do not receive the study intervention may be replaced. Participants who sign the informed consent form, and receive the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study, may be replaced.

## Lost to Follow-up

* The screening, signing of informed consent form and study will all take place on the same day. There will be no follow-up with participants.

# STUDY ASSESSMENTS AND PROCEDURES

## Screening Procedures

### Screening activities performed prior to obtaining informed consent

Minimal risk activities that may be performed before the participant’s parent or guardian has signed a consent include the following:

* Email, written, in person or telephone communications with prospective participants confirming the following:
  + Age
  + English proficiency
  + Willingness and ability to provide informed consent

### Screening activities performed after a consent for screening has been signed

The following activities will be performed only after the participant’s parent or guardian has signed the consent of this study.

## Study Evaluations & Procedures

The study is designed to evaluate the feasibility and accuracy of a non-invasive Doppler sensor for monitoring vital signs in neonates admitted to either the Mother Baby Unit or the NICU. The study will enroll up to 40 NICU patients who meet inclusion criteria.

Recruitment: Recruitment will be conducted by trained study staff. The NICU census will be reviewed by the study PI on a weekly basis to identify potential patients meeting inclusion criteria who can be approached for consent. Advertising will include word of mouth and flyers posted in the NICU parent lounge.

Parent(s) or legal guardian(s) of patients identified for inclusion will be approached in person or over the phone.

Once identified and screened as per 8.1.1, the informed consent form will be reviewed with each participant and study requirements will be covered at that time. Participants will be given an explanation of the process and the study procedures. At that time, each participant will be informed that they can terminate the study early at any point, for any reason and if they wish to proceed, informed consent will be obtained.

A PI or trained study staff will serve as study coordinator during data collection periods.

The study coordinator will connect the traditional (contact-based) monitoring device to a data-collection laptop via a USB cable. Data from the traditional device will be stored on the laptop. The study coordinator will attach the non-invasive doppler sensor to an IV pole at a predetermined distance from the neonate. Data collected by the radar will be stored in memory on the device. Again, there are no elements linking this data to a patient.

Manual measurements of temperature with a thermometer will be collected by the study coordinator every 20 minutes for a total of 3 measurements over a 1 hour period. If the patient is being monitored continuously via thermistor device, the study coordinator will record the temperature displayed by the device every 5 minutes. All vital sign data will be entered into a Redcap data collection form.. Should the device not collect data, the study staff will note it and still record the manual data. There are no elements linking this data to a patient.

The patient will receive routine monitoring with the traditional device as per standard of care. Data from this device will be sent to and stored on the connected laptop. Simultaneously, the doppler sensor will record vital signs including heart rate, respiratory rate and temperature.

Radar and traditional methods will be used to measure and collect data for 1 hour. Non-invasive monitoring will terminate any time it becomes an obstacle to the neonate’s care.

The study coordinator will move the Neo-Guardian device to several predetermined locations relative to the participant. Data will be collected in each location for approximately 20 minutes.

If at any point there is clinical concern for the well being of the participant, the study coordinator will notify the bedside nurse and clinical team to assess the participant.

Rahm Sensor measurements will be compared against measurements obtained using the hospital’s traditional monitoring devices including ECG, respiratory rate, and thermometer.

After data collection is complete the study coordinator will remove the connecting laptop cable, and the Neo-Guardian device. The coordinator will provide a copy of the data to the hospital IT department for hospital records. See section 9 for data analysis.

### Biospecimen Evaluations

N/A

### Correlative Studies for Research/Pharmacokinetic Studies

N/A

### Samples for Genetic/Genomic Analysis

N/A

#### Description of the scope of genetic/genomic analysis

N/A

#### Description of how privacy and confidentiality of medical information/biological specimens will be maximized

* Once consented participants will be assigned a unique identifier.
* The informed consent with the identifier on it will be stored in a locked cabinet at UF Shands.
* All further information collected will only be identified by the unique identifier assigned.

#### Management of Primary Results

* No data will be sent with the participant or to any of their health care providers.

## Safety and Other Assessments

We are working with healthy volunteers who are under no risks greater than everyday normal life risks.

Vital signs will only be collected during the actual study and will include heart rate, respiratory rate and temperature. They will then be compared to the non contact Neo-Guardian vital signs.

## Adverse Events and Serious Adverse Events

### Definition of Adverse Event

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

### Definition of Serious Adverse Events (SAE)

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

### Classification of an Adverse Event

#### Severity of Event

For the purpose of this study, an adverse event will be considered as the appearance or worsening of any undesirable sign, symptom or medical condition occurring after the application of the device.

Any adverse event or concurrent illness experienced by the participant during the study will be evaluated by the investigator and must be recorded in the source documents and Case Report Form. A medical condition that is present at screening and which does not become worse during the study, is not to be considered an Adverse Event and should be recorded in the medical history. A medical condition that is present at screening and worsens during the study should be reported as an Adverse Event. Any Serious Adverse Events that occur within 30 days after the end of the study must be recorded and reported by the investigator to the sponsor and the IRB.

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

* **Mild** – Events require minimal or no treatment and do not interfere with the participant’s daily activities.
* **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
* **Severe** – Events interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious”.

#### Relationship to Study Intervention

All adverse events (AEs) must have their relationship to study intervention assessed by the investigator who examines and evaluates the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

* **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
* **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

#### Expectedness

The investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

### Time Period and Frequency for Event Assessment and Follow-Up

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during the study visit upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician’s assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant’s condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The investigator and/or study staff will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after study participation. Participants will be instructed to call the investigator about the occurrence of worsening undesirable signs, symptoms or medical conditions occurring after the application of the device that may be considered an AE/SAEs since the visit. Events will be followed for outcome information until resolution or stabilization.

In the event a participant experiences an AE/SAE during the study, the study will be discontinued and the clinical team will be immediately notified.

### Adverse Event Reporting

The study investigator will report to the sponsor any adverse event within 7 days, whether or not considered study intervention related, including those listed in the protocol or investigator brochure and must include an assessment of whether there is a reasonable possibility that the study intervention caused the event..

All adverse events (AEs) will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the participant is stable. Other supporting documentation of the event may be requested by the study sponsor and should be provided as soon as possible.

### Serious Adverse Event Reporting

The study investigator will immediately report to the sponsor any serious adverse event, whether or not considered study intervention related, including those listed in the protocol or investigator brochure and must include an assessment of whether there is a reasonable possibility that the study intervention caused the event. Study endpoints that are serious adverse events (e.g., all-cause mortality) must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship between the study intervention and the event (e.g., death from anaphylaxis). In that case, the investigator must immediately report the event to the sponsor.

All serious adverse events (SAEs) will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the participant is stable. Other supporting documentation of the event may be requested by the study sponsor and should be provided as soon as possible.

The study investigator shall complete an Unanticipated Adverse Device Effect Form and submit to the study sponsor as soon as possible, but in no event later than 7 calendar days after the investigator first learns of the effect. The study sponsor is responsible for conducting an evaluation of an unanticipated adverse device effect and shall report the results of such evaluation to the Food and Drug Administration (FDA) and to all reviewing IRBs and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter, the sponsor shall submit such additional reports concerning the effect as FDA requests.

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of all adverse events and shall report the results of such evaluation to the Institutional Review Board (IRB)

### Events of Special Interest

N/A

### Reporting of Pregnancy

N/A

## Unanticipated Problems

### Definition of Unanticipated Problems (UP)

Any incident, experience, or outcome that meets **all** of the following criteria:

* Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied; and
* Related or possibly related to participation in the research (“possibly related” means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
* Suggests that the research places participants or others (which may include research staff, family members or other individuals not directly participating in the research) at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or expected.

### Unanticipated Problem Reporting

The investigator will report unanticipated problems (UPs) to the Institutional Review Board (IRB)

# STATISTICAL CONSIDERATIONS

## Plan for statistical analysis

**Data Preparation:**  
Vital sign data (heart rate, respiratory rate, and temperature) will be recorded simultaneously from the study device and traditional NICU monitors (EKG for heart rate, pulse oximetry for heart and respiratory rate, and standard temperature probes for temperature). Data will be time-synchronized and cleaned to remove artifacts, physiologically implausible values, and missing observations. Only paired data points collected during clinically stable periods will be included.

**Descriptive Statistics:**  
Summary statistics (mean, standard deviation, median, interquartile range) will be calculated for each vital sign from both devices to characterize central tendency and variability within the cohort.

**Agreement and Correlation:**

* **Correlation analysis:** Pearson’s correlation coefficients will be calculated for normally distributed data to assess linear association between Doppler and traditional device measurements. For non-normal data, Spearman’s rank correlation will be used.
* **Bland-Altman analysis:** This method will be applied to assess agreement between measurement methods by estimating bias (mean difference) and limits of agreement (±1.96 SD of the differences). Plots will be examined to identify systematic bias or proportional errors across the measurement range.

**Comparative Statistical Tests:**

* To evaluate systematic differences between methods, paired t-tests will be used if data are approximately normally distributed; otherwise, Wilcoxon signed-rank tests will be applied.

**Subgroup and Sensitivity Analyses:**

* Analyses will be stratified by gestational age categories (normal term, late preterm, low birth weight preterm) to evaluate consistency of device performance across clinically relevant subpopulations.
* Sensitivity analyses excluding outliers or data collected during minor clinical instability will be conducted to assess robustness of findings.

**Power Considerations:**  
Based on prior literature and preliminary data, a sample size of 40 infants with multiple repeated measurements is expected to provide >80% power to detect a mean difference of at least 5 bpm in heart rate and 0.5°C in temperature between devices, assuming a within-subject standard deviation of 8 bpm and 0.7°C respectively, at an alpha of 0.05.

**Statistical Software:**  
All analyses will be conducted using JASP. Graphical analyses and Bland-Altman plots will be generated to visually support quantitative results.

**Statistical Significance:**  
A two-tailed p-value < 0.05 will be considered statistically significant for all inferential tests.

## Statistical Hypothesis

Primary Endpoint(s): Heart Rate, respiratory rate and temperature will be collected with the Neo-Guardian and compared to traditional measurements. The primary endpoint will be the agreement between the Doppler device and standard NICU monitoring for heart rate, measured as the mean difference (bias) and limits of agreement (±1.96 SD) using Bland-Altman analysis. A composite endpoint will be the percentage of infants in whom all three Doppler-derived vital signs (HR, RR, and Temp) fall within predefined clinically acceptable limits compared to standard monitors.

Based on published standards:

* A **mean bias ≤ ±10 bpm** with **95% limits of agreement within ±20 bpm** is considered clinically acceptable for neonatal heart rate monitors.
* Respiratory rate (RR) accuracy thresholds: **≤10% mean difference** and limits within ±10 BrPM.
* Temperature accuracy: **absolute error ≤0.5 °C** (most monitors fall within ~0.06 °C mean error, SD ±0.2 °C).

Sample Size Determination

* Number of participants to pre-screen: 40
* Minimum number of participants to enroll: 20
* Sample size determination: statistician suggested 15-20 participants for a standard pilot study to power future study
* No anticipated dropout rates or withdrawal
* The primary outcome measure is the comparison between traditional measures of HR, RR, and Temp and the devices measurement of HR, RR, and Temp. Mean absolute error will be used as the metric and +/-5% is considered acceptable in this pilot study.
* The null hypothesis is that the device does not measure HR, RR, and Temp as well as traditional measures as defined by a mean absolute error > 5%
* This is a pilot study that will be used to power future studies.

## Populations for Analyses

Healthy volunteers with approximate demographics relative to the population of Gainesville, Florida will be used in this study. The study will use a Per-Protocol Analysis Dataset such that only those who finished the study properly will be analyzed.

### Evaluable for toxicity

N/A

### Evaluable for objective response

N/A

### Evaluable Non-Target Disease Response

N/A

## Statistical Analyses

### General Approach

We will be using descriptive statistics in this pilot study. All data will be continuous and mean absolute error between the device and the standard methods will be compared using mean absolute error.

### Analysis of the Primary Endpoints

The primary outcome measure is the comparison between traditional measures of HR, RR, and Temp and the devices measurement of HR, RR, and Temp. Mean absolute error will be used as the metric and +/-5% is considered acceptable in this pilot study.

### Analysis of the Secondary Endpoint(s)

N/A

### Safety Analyses

There are no known safety risks associated with this technology.

### Baseline Descriptive Statistics

N/A

### Planned Interim Analyses

N/A

### Sub-Group Analyses

N/A

### Tabulation of individual Participant Data

No individual participant data will be listed by measure and time point.

### Exploratory Analyses

N/A

# REGULATORY AND OPERATIONAL CONSIDERATIONS

## Informed Consent Process

### Consent/Assent Procedures and Documentation

* Consent will be obtained at UF Shands
* The PI or study staff can review the ICF and obtain consent.
* While reviewing the consent, each participant will be informed that they can terminate the study early at any point, for any reason with no penalty to them.
* Consent will be done in person with review of the consent form with the participant by the PI and study staff, confirmation that they understand and signing of the ICF.
* A hard copy of the consent will be provided to the participants before signing.
* Once the consent form is reviewed with the participant, they will be asked if they understand, and given as much time as they need before signing to agree to participate in the study.
* Parents or legal guardians of eligible infants will be approached in person or via remote consent by trained research staff following confirmation of eligibility and clinical stability. Consent will be obtained in a private setting and at a time when the family is not actively engaged in clinical care discussions. Parents will be provided written informed consent materials and a verbal explanation of the study's purpose, procedures, and voluntary nature.
* A screening and enrollment log will be maintained to track demographic characteristics, enrollment status, and balance across gestational age and skin tone categories. Weekly internal reviews will ensure that enrollment targets are being met and adjustments can be made if needed.

### Considerations for Consent of staff, or family members of study team members

Consent for staff will be obtained as detailed above with following additional protections:

Consent from staff members will be obtained by an individual independent of the staff member’s team whenever possible. Otherwise, the consent procedure will be monitored in order to minimize the risk of undue pressure on the staff member.

## Study Discontinuation and Closure

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, sponsor and the IRB. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

* Determination of unexpected, significant, or unacceptable risk to participants
* Demonstration of efficacy that would warrant stopping
* Data that are not sufficiently complete and/or evaluable
* Determination that the primary endpoint has been met
* Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the sponsor, IRB and, as applicable, the Food and Drug Administration (FDA).

## Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s). This will cover the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

Consent review and obtaining written consent will happen in the mother’s room at UF Shands.

Authorized representatives of the sponsor, representatives of the Institutional Review Board (IRB), and/or regulatory agencies may inspect all documents and records required to be maintained by the investigator, including but not limited to, ICF and data collected 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 in a locked cabinet at UF Shands 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 the reviewing IRB, Institutional policies, or sponsor requirements.

Study participant research data, which is for purposes of statistical analysis will be stored on a password protected laptop at UF Shands. 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.

If any publications are created, no information will be published that would identify any participants, it will only be data collected. Unique identifiers will not be shared.

## Safety Oversight

As the risk of this pilot study is no greater than every day normal activities, is completed in 1 day for approximately 1.5 hours no safety oversight board will be assigned.

## Clinical Monitoring

Since the risk of this pilot study is no greater than every day normal activities and is completed in 1 day lasting approximately 1.5 hours, no safety clinical monitor will be assigned.

## Quality Assurance and Quality Control

The clinical site will perform internal quality management of study conduct, data, documentation and completion. The PI and one staff member will each review data collected for errors and the PI will address any data collection questions from the sponsor.

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 the sponsor, and inspection by local and regulatory authorities.

## Data Handling and Record Keeping

### Data Collection and Management Responsibilities

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the 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.

Hardcopies of the study CRF will be provided for use as source document for recording data for each participant enrolled in the study.

Clinical data (including adverse events (AEs), and expected adverse reactions data) will be kept on site at UF Shands. The data system includes password protection.

### Study Records Retention

Study documents should be retained for a minimum of 2 years after the last approval of a marketing application in an International Council on Harmonisation (ICH) region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

## Protocol Deviations and Non-Compliance

It is the responsibility of the investigator to use continuous vigilance to identify and report deviations and/or non-compliance to the Institutional Review Board. All deviations must be addressed in study source documents, reported to the IRB if requested. The investigator is responsible for knowing and adhering to the reviewing IRB requirements.

### NIH Definition of Protocol Deviation

A protocol deviation is any change, divergence, or departure from the IRB-approved research protocol.

* Major deviations: Deviations from the IRB approved protocol that have, or may have the potential to, negatively impact the rights, welfare or safety of the participant, or to substantially negatively impact the scientific integrity or validity of the study.
* Minor deviations: Deviations that do not have the potential to negatively impact the rights, safety or welfare of participants or others, or the scientific integrity or validity of the study.

## Human Data Sharing, including Genomic Data Sharing, and Publication

### NIH Data Management and Sharing Policy and NIH Genomic Data Sharing Policy Compliance

N/A

### NIH Public Access Policy Compliance

N/A

## Conflict of Interest Policy

*This section should include a description of how the study will manage actual or perceived conflicts of interest.*

*Example text provided as a guide, customize as needed:*

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

There are no perceived conflicts of interest with the PI or study staff.

ABBREVIATIONS

*The list below includes abbreviations utilized in this template. However, this list should be customized for each protocol (i.e., abbreviations not used should be removed and new abbreviations used should be added to this list).*

|  |  |
| --- | --- |
| AE | Adverse Event |
| ANCOVA | Analysis of Covariance |
| CFR | Code of Federal Regulations |
| CLIA | Clinical Laboratory Improvement Amendments |
| CMP | Clinical Monitoring Plan |
| COC | Certificate of Confidentiality |
| CONSORT | Consolidated Standards of Reporting Trials |
| CRF | Case Report Form |
| DCC | Data Coordinating Center |
| DHHS | Department of Health and Human Services |
| DSMB | Data Safety Monitoring Board |
| DRE | Disease-Related Event |
| EC | Ethics Committee |
| eCRF | Electronic Case Report Forms |
| FDA | Food and Drug Administration |
| FDAAA | Food and Drug Administration Amendments Act of 2007 |
| FFR | Federal Financial Report |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practices |
| GMP | Good Manufacturing Practices |
| GWAS | Genome-Wide Association Studies |
| HIPAA | Health Insurance Portability and Accountability Act |
| HR | Heart Rate |
| IB | Investigator’s Brochure |
| ICH | International Council on Harmonisation |
| ICMJE | International Committee of Medical Journal Editors |
| IDE | Investigational Device Exemption |
| IND | Investigational New Drug Application |
| IRB | Institutional Review Board |
| ISM | Independent Safety Monitor |
| ISO | International Organization for Standardization |
| ITT | Intention-To-Treat |
| LSMEANS | Least-squares Means |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MOP | Manual of Procedures |
| MSDS | Material Safety Data Sheet |
| NCT | National Clinical Trial |
| NIH | National Institutes of Health |
| NIH IC | NIH Institute or Center |
| OHRP | Office for Human Research Protections |
| PI | Principal Investigator |
| QA | Quality Assurance |
| QC | Quality Control |
| RR | Respiratory Rate |
| Rahm | Rahm Sensor Device |
| SAE | Serious Adverse Event |
| SAP | Statistical Analysis Plan |
| SMC | Safety Monitoring Committee |
| SOA | Schedule of Activities |
| SOC | System Organ Class |
| SOP | Standard Operating Procedure |
| Temp | Temperature |
| UP | Unanticipated Problem |
| US | United States |

# REFERENCES

Xandar Kardian 510(k)[*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202464*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202464)

VetGuardian web site <https://zom-dx.zomedica.com/Products/vetguardian/>

**APPENDIX A**

**VetGuardian (VG) Beta-Testing for one month**

**APPENDIX B**

**Validation and Method Comparison for a Zero-Touch Monitoring Device**