



Clinical Study Protocol

Rosella APM: A prospective, multicenter, single-arm study examining the Assisted Programming Module (APM) in the Evoke Spinal Cord Stimulation (SCS) System to program patients with chronic pain of the trunk and/or limbs.

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Sponsor:

Saluda Medical Americas, Inc.

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1 CLINICAL PROTOCOL SUMMARY

Title	Rosella APM Study: A prospective, multicenter, single-arm study evaluating the use of the Assisted Programming Module (APM) in the Evoke Spinal Cord Stimulation (SCS) System to program patients with chronic pain of the trunk and/or limbs.
Investigational Feature	The Evoke Spinal Cord Stimulator (SCS) System (Evoke System) has FDA approval as an aid in the management of chronic intractable pain of the trunk and/or limbs and will be used within its commercially approved indication. An investigational programming software module, the Assisted Programming Module (APM), which provides an optional assisted programming workflow that guides the Clinical System operator through the programming of closed-loop therapy in patients with the Evoke System, will be investigated in this study.
Purpose	The purpose of this study is to investigate a new programming software module, the Assisted Programming Module (APM), which provides an optional assisted programming workflow that guides the Clinical System operator through the programming for closed-loop therapy in patients with the Evoke System.
Study Design	This study is a prospective, multicenter, single-arm study. Data will be collected at programming visits, telephone follow-ups post-programming, and at 1-month and 3-month visits (post-permanent implant initial programming). Post-3-month visits, in the extended follow-up phase, will be completed only as needed based on re-programming.
Primary Objective	The primary objective of the study is to evaluate the use of APM in a real-world population of US patients with the Evoke System.
Data Collection	The following data will be collected: • Feedback on the use of the APM • Data collected directly on the device, including programming parameters and characteristics and neurophysiological measurements • Safety, including related adverse events, device deficiencies, and protocol deviations
Statistical Analysis	This exploratory clinical investigation does not have a pre-specified formal statistical hypothesis. A number of outcomes of interest will be collected and assessed across study visits. Descriptive statistics and/or exploratory modelling will be utilized.
Inclusion Criteria	Subjects enrolled in this study must meet all of the following inclusion criteria (based on investigator judgement): 1. Subject has or is planning to have a temporary trial with the Evoke System within the FDA approved indication. 2. Subject is willing and capable of giving informed consent and able to comply with study-related requirements.
Exclusion Criteria	N/A
Investigation Sites	Up to 5 US sites.
Enrollment	Enrollment is defined as providing informed consent and participation in the initial programming session with the investigational APM during the trial phase. Up to 30 subjects will be enrolled. Enrollment is anticipated to take 12 months.

2 BACKGROUND

The safety and performance of SCS systems is based on a foundation of over 50 years of clinical research and experience with SCS systems. This therapy has been accepted internationally through market approval of SCS systems and is recognized by national medical societies as an appropriate treatment for chronic pain of the trunk and/or limbs. SCS is a well-established therapy with a long history of use in treating chronic intractable pain of the trunk and/or limbs.

SCS consists of applying an electrical stimulus to the spinal cord which causes the activated fibres (e.g., A β -fibres) to generate action potentials. A β -fibres are the low-threshold sensory fibres in the dorsal column that contribute to inhibition of pain signals in the dorsal horn. The action potentials summed together form the electrically evoked compound action potential (ECAP). Therefore, ECAPs are a direct measure of spinal cord fibre activation that generates pain inhibition for an individual.

The FDA-approved (and CE Marked) Evoke System has the advantage over the other SCS systems currently on the market in that it measures ECAPs and offers closed-loop stimulation through a feedback control mechanism, which uses ECAPs to adjust stimulation and automatically keep the therapy near the patient's preferred level. The performance of the device has been demonstrated through the extensive clinical testing (1,2), the evidence of which resulting in market approval in the United States, Europe, and Australia.

2.1 Rationale for the Clinical Study

As part of the Saluda Medical's commitment to continually improve and streamline its products, this clinical study aims to evaluate the use of the new Assisted Programming Module (APM) in programming patients with the Evoke System in a real-world US population.

3 DEVICE DESCRIPTION AND INDICATION FOR USE

3.1 Device Description

The Saluda Medical Evoke® Spinal Cord Stimulation System has received FDA approval for the treatment of chronic intractable pain of the trunk and/or limbs; refer to the FDA website for the most current information on the approved products (<https://www.fda.gov/medical-devices/recently-approved-devices/evoke-spinal-cord-stimulation-scs-system-p190002>).

The commercially available product manuals or Instructions for Use (IFUs) can be found on Saluda Medical's website <https://www.saludamedical.com> under Product Manuals.

Saluda Medical's commercially approved Clarity™ Programming Application (CPA) is a software application which runs on the Evoke® Clinical Interface, a Microsoft Surface Pro tablet. The CPA is used by a Clinical System operator in either the operating room or clinic environment to identify, test, and deploy a set of therapeutic stimulation programs which the Evoke Closed-Loop Stimulator (pulse generator) or External Closed-Loop Stimulator will store and execute.

3.1.1 Investigational Features

This study is investigating an update to the programming software which includes the addition of a new software module, the Assisted Programming Module (APM). The APM provides an optional assisted programming workflow that guides the Clinical System operator through the same workflow steps that would be performed manually during a programming session for closed-loop therapy (open-loop therapy will continue to be configured manually). The APM has two modes of operation:

- With the New Program Assistant, the APM suggests a program for a patient's therapy.
- With the ECAP Assistant, the APM suggests program adjustments based on the stimulation configuration of an existing program.

These updates to the CPA are intended to streamline initial stimulation parameter selection and updates to existing programs by suggesting parameter values commonly selected for patients in the Evoke Study (G150266). There are no changes to the programming parameters made available to the programming clinician. The patients will receive stimulation programs with parameters (e.g., stimulation frequency, pulse width) that are within currently commercially approved settings and can continue to have a choice of multiple programs as needed.

Minor updates to the stimulator firmware (CLS and eCLS) were also made to provide compatibility with the CPA updates.

3.2 Target Indication for Use

The Evoke System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

4 STUDY PURPOSE AND OBJECTIVES

4.1 Study Purpose

The purpose of this study is to investigate a new programming software module, the Assisted Programming Module (APM), which provides an optional assisted programming workflow that guides the Clinical System operator through the programming for closed-loop therapy in patients with the Evoke System.

4.2 Primary Objectives

The primary objective of the study is to evaluate the use of the APM in a real-world population of US patients with the Evoke system.

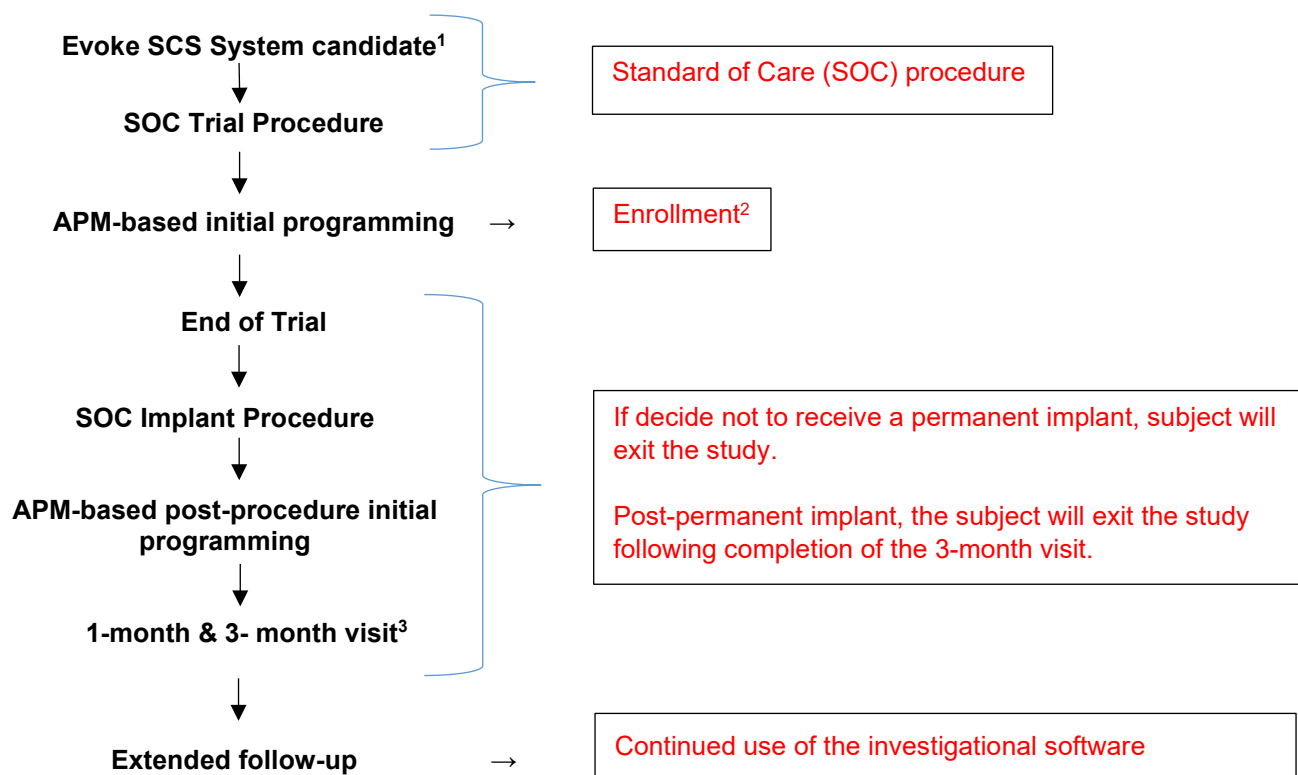
5 STUDY DESIGN

This study is a prospective, multicenter, single-arm study designed to evaluate the use of the Assisted Programming Module (APM) for programming patients who received the Evoke System within its commercially approved indication.

Patients will undergo the trial and permanent implant procedures of the Evoke System per standard of care and in accordance with the Evoke IFU.

Subjects who provide informed consent and undergo a programming session with APM will be enrolled. Data will be collected at each programming session, telephone follow-ups post-programming, and at the 1-month and 3-month visits following the post-permanent implant initial programming. Subjects may choose to exit the study post 3-month visit and have their software converted to commercially approved software or subjects may consent to extended follow-up and use of the investigational software until FDA approval.

Figure 1: Study Design



¹Informed Consent may occur pre- or post-trial; it may occur anytime prior to the initial programming session with the investigational APM during the trial phase.

²Enrollment is defined as providing informed consent and participation in the initial programming session with the investigational APM during the trial phase.

³At the time of the 3-month visit, the subject can choose to revert to commercially approved software or consent to the extended follow-up.

6 STUDY POPULATION

6.1 Study Sites

Study subjects will be enrolled at up to 5 US sites.

6.2 Inclusion Criteria

To be eligible to participate in this study, a subject must meet all the following criteria, as determined by the Investigator:

1. Subject has or is planning to undergo a temporary trial with Evoke System within the FDA approved indication.
2. Subject is willing and capable of giving informed consent and able to comply with study-related requirements.

6.3 Exclusion Criteria

There are no exclusion criteria.

7 STUDY ASSESSMENTS

7.1 Programming Assessments

Device programming will initially occur following the trial and implant procedures. Programming adjustments may occur multiple times after initial programming (for either the trial or the permanent implant) in order to optimize treatment.

Programming will be performed by the Sponsor representative utilizing the APM software module. If necessary, manual adjustments may be made by the Sponsor representative thereafter in accordance with the IFU.

At all programming sessions, neurophysiological measurements of the stimulated fibers (e.g., ECAP features), program parameters (e.g., frequency, pulse width, stimulation amplitude) and characteristics (e.g., usage) will be collected via automatic recordings on the device logs.

The following assessments may be collected at each programming session:

- Feedback on the use of APM.
- Questions about stimulation sensation.
- Data on stimulation intensity and ECAP amplitude at various stimulation levels (i.e., activation plot of perception threshold, comfort, and maximum) and in different postures. Subjects will rate the stimulation intensity on an 11-point numeric rating scale (0 equals “no feeling” and 10 equals “very intense”). All data will be recorded on device logs, except subject ratings, which will be recorded on the CRF.

7.2 Follow-up (Telephone, 1-Month, 3-Month)

At telephone follow-ups (within approximately two weeks after each programming session) and at the 1-month (30, -14 days, +21days) and 3-month (90±21 days) in-clinic visits post-permanent implant initial programming, the Sponsor Representative will assess the subject’s stimulation therapy and device functionality. If the 1- or 3-month visit are within two weeks of a programming session, then they may be completed in lieu of the telephone follow-up.

The following assessments may be collected at telephone and in-clinic follow-up visits:

- Device programming issues or concerns.
- APM program usage and satisfaction.
- Feedback on the use of the APM.

Extended Follow-Up Phase: Subjects will be offered continued use of the APM software if they consent to the extended follow-up phase. There are no required study visits during this phase. Re-programming visits may occur, as needed. Device data will continue to be collected automatically on the system.

8 STUDY PROCEDURES

8.1 Visit Schedule

Table 1. Required Protocol Assessments

Protocol Assessments	Screening	Temporary SCS Trial Phase	Permanent SCS Implant Phase			
	Screening	Trial Phase Programming ²	Implant Phase Programming ²	1 Month (30 days -14 days, +21 days)	3 Month (90 days ± 21 days)	Extended Follow-up
Informed Consent & Inclusion/Exclusion	X					
Programming ¹		X	X	O	O	O
Follow-up		X	X	X	X	
Safety ³		X	X	X	X	X

X= Required; O=Optional, as needed

¹Reprogramming may occur as needed for optimization throughout the study. Data Collection at each programming visit is required for patients, and at least once during the study for clinicians; Sponsor Representatives/FCEs feedback will be collected as applicable.

²Initial programming will occur following the trial procedure and following the permanent implant procedure. The initial programming during the implant phase is Day 0 for calculating the follow-up visit windows.

³Includes evaluation for potential adverse events, device deficiencies, and protocol deviations.

8.2 Study Exit – Completion and Withdrawal

At the end of the subjects' study participation, either due to study completion or early withdrawal, a study exit form will be completed documenting the date and reason for study exit. If the subject decides not to receive the permanent implant, their participation in the study will be complete and they will exit the study at that time.

Post-permanent implant, the subject's participation in the study will be complete following the 3-month visit unless the patient consents to the extended follow-up phase. If a subject consents to extended follow-up, which is through FDA approval of the APM software, expected within 2 years, there are no further required visits. The subject can continue to be programmed, as needed, using the investigational software. Upon FDA approval, the subject will be provided with the approved version and will exit the study at that time. The study exit form is only required for enrolled subjects; patients who consent but do not undergo an APM programming session will be considered screen failures. For subjects who withdraw from the study early, all attempts will be made to collect safety data.

9 ADVERSE EVENTS

9.1 Adverse Event Definitions

9.1.1 Adverse Event

An **adverse event (AE)** is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs in subjects, whether or not related to the investigational medical device.

9.1.2 Serious Adverse Event

A **serious adverse event (SAE)** is defined as an AE that

- Led to death,

- Led to serious deterioration in the health of the subject, and that either resulted in:
 - a life-threatening illness or injury, or
 - a permanent impairment of a body structure or a body function, or
 - prolonged hospitalization, or
 - medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
- Led to fetal distress, fetal death, or congenital anomaly or birth defect.

Note: Planned hospitalization for a pre-existing condition or a hospitalization without serious deterioration in health, is not considered an SAE.

9.1.3 Unanticipated Adverse Device Effects

An **unanticipated adverse device effect (UADE)** means any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigation plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

An event will not be considered a UADE if it is a known consequence of the underlying disease or condition under investigation, surgery, or other events that commonly occur in the study population independent of the investigational device.

The final determination of whether an AE meets the definition of a UADE will be made by the independent adjudication committee for this study.

9.2 Adverse Event Recording and Reporting

9.2.1 Adverse Event Recording

Investigators are responsible for providing a description of all device-related AEs, including the clinical outcome for the subject. Investigators will evaluate each event for seriousness, severity, and relatedness to the device or stimulation therapy. Investigators must supply the Sponsor with any additional information related to safety reporting of a particular event.

9.2.2 Adverse Event Reporting

Investigators are required to report device-related AEs from the time of the initial APM programming session (except as outlined below). If an AE leads to multiple outcomes that sequentially worsen, only the worst AE will be reported.

Investigators shall report AEs to the Sponsor, and to their reviewing IRB per the IRB's reporting requirements. Investigators are required to report UADEs to the Sponsor and their reviewing IRB as soon as possible, but in no event later than 10 working days after the Investigator first learns of the effect, per 21 CFR 812.150 (refer to section 13.7.2 for Investigator reporting requirements).

AE reporting exceptions:

- AEs associated with the procedure, related or unrelated, will not be collected in this study as the SCS trial and implant procedures are not part of the study (not investigational). The trial and permanent implant procedure will be conducted according to standard of care and in accordance with the Evoke IFU.
- Lack of efficacy, by itself, does not constitute an AE since failure to receive therapeutic benefit is an issue of efficacy, which is not being evaluated in this study, not safety.
- Loss of therapy/stimulation does not constitute an AE unless an untoward medical occurrence results.

- A subject's perception of the stimulation induced feeling of stimulation sensation is called paresthesia. There are well-known challenges associated with optimizing SCS such as changes in stimulation intensity and stimulation in unwanted areas. These will not be reported as AEs unless the Investigator determines the nature and/or severity is outside what is typical for neurostimulation.
- Temporary changes in symptoms and stimulation that are alleviated with programming will not be reported as AEs unless the Investigator determines the nature and/or severity is outside what is typical for neurostimulation.

9.3 Independent Medical Reviewer and/or Adjudication Committee

Independent medical reviewer and/or adjudication committee will be responsible for the review, evaluation, categorization, and adjudication of all AEs that are reported during the clinical study. AEs will be reported based on this adjudication.

10 DEVICE DEFICIENCIES

10.1 Device Deficiency Definitions

A device deficiency is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies include malfunctions, use errors, and inadequate labelling.

10.2 Device Deficiency Reporting

The Investigator shall report all suspected device deficiencies to the Sponsor. Device deficiencies will not necessarily result in an AE. However, if an AE is associated with a device deficiency, the AE shall be documented and reported.

11 STATISTICAL ANALYSIS

11.1 Sample Size

With 30 subjects, there is a greater than 80% probability of observing one or more events, for events that occur at a population rate of 5.3% or higher.

11.2 Study Outcomes

A number of outcomes of interest will be collected and assessed across study visits to characterize the APM.

11.3 General Statistical Procedures

The following general statistical methods will be employed to assess the study data:

- There are no pre-planned formal statistical hypothesis tests.
- Standard summary statistics will be used to summarize key study variables. Categorical variables will be summarized via incidence and percent. Continuous variables will be summarized via mean, median, standard deviation, and range.
- Findings of significance may be presented and include p-values and/or 95% confidence intervals as appropriate.
- Standard tests for significance will be employed, including one sample t-tests. Additional exploratory analyses may be performed and include correlation analysis, linear and logistic

regression analyses, repeated measures analyses, and generalized estimating equation (GEE) analyses as appropriate.

- Unless stated otherwise, statistical significance is defined as achieving a p-value less than 0.05. P-values will be nominal and not adjusted for multiplicity.
- In the event planned parametric methods are found to be inappropriate based upon observed distributions of individual variables, appropriate non-parametric methods will be employed.
- The incidence of all distinct AEs will be presented. AEs will also be summarized by seriousness, severity, and relatedness to the device. AEs will be reported based on the adjudication committee determination.

11.4 Timing of Analyses

As there are no formal pre-planned hypothesis tests, statistical analyses may be completed at any time. Reporting will be completed as required per the regulations and governing IRBs.

12 RISK ANALYSIS

12.1 Potential Risks

This study qualifies as a Non Significant Risk (NSR) study as the investigational device does not meet the definition of a significant risk device as provided in 21 CFR 812.3(m) and for the following reasons:

- Apart from the update to the CPA, the study will be using the fully commercially approved Evoke SCS System (P190002) for its intended use as a treatment for chronic pain of the trunk and limbs. The trial and implant procedures and devices are unchanged.
- The programming parameters available with the APM are unchanged from those currently approved and commercially available with the Evoke System. Only the programming process is being streamlined. Final programs continue to be confirmed by the patient and clinician prior to deployment.
- The APM is not intended to support or sustain human life and does not present a potential for serious risk to the health, safety, or welfare of a subject.
- The APM is not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does not present a potential for serious risk to the health, safety, or welfare of a subject.
- The APM does not otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

All predictable risks associated with the Evoke System have been identified and mitigated or minimized with residual risk disclosed within FDA approved labelling. The overall risk profile of the Evoke SCS system with APM under this investigation is not different to the overall risk profile of the FDA-approved Evoke System.

12.2 Minimization of Risks

All known and foreseeable risks associated with the Evoke System and the APM have been identified and mitigated with appropriate risk controls to reduce the risk as far as possible.

Risks in this study will be minimized by strict compliance with this protocol, and adherence to the guidelines for subject selection, site training, and close monitoring of the subject status. In addition, the product labeling details instructions for device use, risks, warnings and precautions, which must be followed to minimize risk to subjects. Additionally, device programming will be performed by a trained Sponsor representative with the oversight of the Investigator.

12.3 Potential Benefits

The Evoke SCS System has been commercially approved for the management of chronic pain of the trunk and/or limbs. The APM may or may not benefit the subject. This new programming application is intended to streamline the programming process.

12.4 Benefit-Risk Conclusions

SCS has been used for over 50 years to aid in the management of chronic, intractable pain of the trunk and limbs. The commercially available Evoke System will be used in this study. The programming parameters available with the APM are unchanged from the commercially available system; the changes that have been made are related to streamlining the programming process. All risk control measures identified for the addition of the APM to reduce the risk as far as possible have been verified or validated through Saluda risk management procedures and relevant testing. Therefore, the risks associated with participation in this study are outweighed by the potential benefits and value of the research.

13 STUDY ADMINISTRATION

13.1 Study Materials

13.1.1 Packaging and Labeling

In accordance with 21 CFR Part 812, the study device or its immediate package will bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with 21 CFR Part 801), the quantity of contents, if appropriate, and the following statement: "CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use." Labeling describing all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions are provided in the IFU.

13.1.2 Handling and Storage

The Investigator must ensure that the study devices are controlled and stored according to the IFU. All supplies are to be used only for this study protocol and not for any other purpose. Products are not to be used after the expiration date indicated on the label. The Investigator must not destroy any unused supply unless instructed by the Sponsor.

13.1.3 Product Accountability

The Investigator is responsible for study device accountability, reconciliation, and record maintenance. The Investigator must maintain study device accountability records throughout the course of the study.

13.2 Ethics

13.2.1 Institutional Review Board Approval

The protocol, informed consent form (ICF) and authorization for the use and disclosure of health information per the Health Insurance Portability Accountability Act (HIPAA) must be approved by the investigation site's Institutional Review Board (IRB) before subject enrollment. Changes to the protocol must be approved in writing by the Sponsor and the IRB (as applicable) before the change is implemented.

A copy of the IRB approval letter (and approved ICF and subject materials) must be submitted to the Sponsor. Investigators are responsible for submitting and obtaining initial approval and continuing approval of the study from the IRB and forwarding copies of the approval documentation to the Sponsor.

13.2.2 Informed Consent

The Investigator will prepare an ICF in accordance with this study protocol, regulatory requirements (21 CFR Part 50), Good Clinical Practices (GCP), and the ethical principles that have their origin in the Declaration of Helsinki using the sample ICF provided in Appendix A of this study protocol.

As part of the consent process, the subject will have ample time and opportunity to ask questions of, and receive answers from the personnel conducting the study, and to decide whether to participate in the study. The information that is given to the subject shall be in language understandable to them. Neither the Investigator nor the investigation site personnel shall coerce or unduly influence the subject to participate or continue to participate in the study.

All subjects must document their consent for study participation and authorization for use and disclosure of health information by signing the IRB-approved ICF. The Investigator will retain the original ICF signed by the subject and a copy of the ICF will be provided to the subject.

The Sponsor will inform the Investigator whenever information becomes available that may be relevant to the subject's consent, and will revise the ICF accordingly and provide it to the Investigator for approval by the IRB. The Investigator or his/her authorized designee shall inform the subject of this information. After approval by the IRB, a copy of this ICF must be provided to the participating subjects, and the informed consent process as described above repeated, in accordance with the IRB requirements.

13.2.3 Subject Confidentiality

The Sponsor and its designees will make every reasonable effort to protect the confidentiality of the subjects participating in the study. Only Sponsor personnel or contracted agents of the Sponsor will have access to these confidential files and will act in accordance with applicable regulations as required by HIPAA. The IRBs and FDA also have the right to inspect and copy all records pertinent to this study. All data used in the reporting of the study will eliminate any identifiable reference to the subjects.

13.3 Data and Quality Management

This study will be conducted in accordance with the regulatory requirements, GCP, and the ethical principles that have their origin in the Declaration of Helsinki. The study shall not begin until receipt of the required approval from the reviewing IRB. Any additional requirements imposed by the IRB shall be followed as appropriate.

13.3.1 Data Collection and Management

Subject data will be collected and entered in an electronic data capture (EDC) system specifically created for this study in accordance with this study protocol, regulatory requirements (21 CFR Part 11), and GCP. Data may be reviewed by the Sponsor using programmed or manual queries to ensure accuracy of the data entered and minimize the occurrence of missing data. Data management activities will be specified in the Data Management Plan.

To minimize the study burden on the site staff/investigator while maintaining integrity and quality of the data and safety of the patients, data that has documented source (e.g., CRF worksheets) may be entered into the EDC system by the sponsor representative/field clinical engineer (FCE) or the site staff, but will require investigator oversight via eSignature in the database. Accurate documentation supports the fundamental principle of protecting subjects' rights, safety and well-being and will be adhered to. The investigator's e-signature verifies oversight of the study, and that the data is accurate, attributable, and contemporaneous.

System/device data (data collected directly on the system/device) will be automatically generated/collected and analyzed independently. Data is continuously collected on the SCS system while the patient is outside the clinic and will be collected automatically.

13.3.2 Monitoring

The study will be monitored to ensure the rights and well-being of human subjects are protected; the reported study data are accurate, complete, and verifiable from source documents; and the conduct of the study is in compliance with the study protocol, regulatory requirements, GCP, Declaration of Helsinki, and any conditions of approval imposed by the reviewing IRB. Monitors will be qualified by training and experience to monitor the study in accordance with these requirements. Monitoring activities will be conducted in accordance with the Monitoring Plan.

13.3.3 Audits/Inspections

Audits of the investigation sites may be performed by the Sponsor or designee, independent of and separate from routine monitoring or quality control functions, to evaluate study conduct and compliance with the study protocol, applicable regulatory requirements, GCP, Declaration of Helsinki, and any conditions of approval imposed by the reviewing IRB.

The FDA or other regulatory agencies may perform inspections of the investigation sites before, during, or after the conclusion of the study. The Investigator shall contact the Sponsor immediately upon notification of inspection, and must fully cooperate with the regulatory agency by permitting inspections at reasonable times and in a reasonable manner.

13.4 Access to Study Records

The Investigator must permit monitoring and auditing by the Sponsor or designee, and inspection by the appropriate regulatory authorities, and provide direct access to all requested study-related records.

13.5 Investigation Site and Subject Training

All primary site personnel (Investigator(s) and core site staff) will be trained on the study protocol and the applicable Code of Federal Regulations (CFRs). Support staff may be trained minimally based on delegated tasks.

13.6 Investigator Responsibilities

The Investigator is responsible for ensuring the study is conducted according to the signed Clinical Trial Agreement (CTA)/Investigator Agreement (IA), study protocol, regulatory requirements, GCP, Declaration of Helsinki, and any conditions of approval imposed by the reviewing IRB; for protecting the rights, safety, and welfare of subjects under the Investigator's care; and for the control of devices under investigation.

13.7 Investigator Agreement and Financial Disclosure

The Principal Investigator (PI) at each site will be required to sign the Investigator's Agreement, as per 21 CFR Part 812.

In addition, in accordance with 21 CFR Part 54, all Investigators will be required to sign a Financial Disclosure form, which certifies or discloses the Investigator's and his/her immediate family's financial interests and arrangements with Saluda Medical. Investigators must inform the Sponsor of any changes to the information within the financial disclosure throughout the course of the study and for a period of two years after the device is approved by the FDA or the study is terminated, whichever is later.

13.7.1 Investigator Records

Records to be maintained by the Investigator in the investigation site's essential study files for this study include, but are not limited to:

- Study protocol and all amendments
- Signed IA for the PI
- Signed Financial Disclosure for all Investigators
- IRB approval letter(s) including approved consent and HIPAA authorization form(s), and subject materials
- IRB Membership list(s) or Letter of Assurance
- All relevant correspondence relating to the study between the site and Sponsor, the site and IRB
- Curriculum Vitae (CV) for all Investigators
- Training documentation
- Delegation of Authority
- Investigational device accountability records including: date, quantity, lot/serial numbers of all devices, identification of all persons the device was used on and final disposition

The following records must be maintained for each subject enrolled in the study:

- Signed ICF and Authorization for the Use and Disclosure of Health Information
- AEs and any supporting documentation
- Protocol deviations
- Source documentation: complete medical records, including procedure reports, professional notes, etc.

13.7.2 Investigator Reports

Investigators are required to prepare and submit the following complete, accurate, and timely reports:

- An Investigator shall submit to the Sponsor and to the reviewing IRB a report of any **UADE** occurring during an investigation as soon as possible, but in no event later than 10 working days after the Investigator first learns of the effect.
- An Investigator shall report to the Sponsor, within 5 working days, a **withdrawal of approval by the reviewing IRB** of the Investigator's part of an investigation.
- An Investigator shall submit **progress reports** on the investigation to the Sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.
- An Investigator shall notify the Sponsor and the reviewing IRB of any **deviation from the investigational plan** to protect the life or physical well-being of a subject in an emergency. Such notice shall be given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the Sponsor is required for changes in or deviations from a plan.
- If an **Investigator uses a device without obtaining informed consent**, the Investigator shall report such use to the Sponsor and the reviewing IRB within 5 working days after the use occurs.
- An Investigator shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

13.8 Sponsor Responsibilities

Saluda Medical Americas, Inc. will serve as Sponsor of this clinical investigation and is responsible for selecting qualified Investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, ensuring that any reviewing IRB are promptly informed of significant new

information about an investigation, as required in 21 CFR 812 Subpart C, and for Sponsor records and reports outlined in 21 CFR Part 812 Subpart G.

13.8.1 Sponsor Representatives

Sponsor representatives may participate in the conduct of the trial to the extent described in this protocol. Participation in the study will be limited to Sponsor personnel who are appropriately trained. Sponsor representatives will operate equipment during the procedures and follow-up, and interact with the subject to accomplish procedure and programming activities under the direction of a healthcare professional. Typical tasks may include:

- Interrogating and downloading the device data
- Programming device parameters
- Clarifying device behavior, operation, or diagnostic output
- Collection of study data from the device and/or programming
- Entering data on study worksheets for programming and follow-up visits
- Collection of feedback on the use of the APM
- Recording any device deficiencies or product accountability
- EDC data entry when source documentation (e.g., CRF worksheets) are available

The Sponsor representatives may contact the subject at any time to check on their stimulation therapy and device functionality. Based on this interaction, additional training or troubleshooting may be provided or the subject may be asked to come into the clinic for reprogramming or troubleshooting. If unsolicited information is reported by the subject that is outside the technical nature of the device, the subject will be advised to contact the Investigator.

At no point shall personnel from the Sponsor:

- Practice medicine
- Provide medical diagnosis or treatment to subjects
- Discuss a subject's medical condition or treatment with a subject without the oversight of a healthcare professional

13.9 Deviations to the Protocol

An Investigator is required to conduct this study in accordance with the signed CTA/IA, study protocol, regulatory requirements, GCP, Declaration of Helsinki, and any conditions of approval imposed by the reviewing IRB.

In accordance with FDA regulation 21 CFR Part 812.150(a)(4), the Investigator shall notify the Sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice shall be given as soon as possible, but no later than five working days after the emergency occurred.

All deviations from the study protocol must be reported to the Sponsor. Except in an emergency, prior approval by the Sponsor is required for an anticipated change in or deviation from the plan and, if these changes or deviations could affect the rights, safety or welfare of human subjects, the reviewing IRB approval must be notified no later than 5 working days after the emergency occurred in accordance with 21 CFR Part 812.150(a) (4).

13.10 Amendments to the Protocol

Any amendments to the study protocol will be clearly documented and approved by the Sponsor and the IRB prior to implementation.

13.11 Completion, Early Termination, or Suspension of the Study

The Sponsor reserves the right to suspend or terminate the study at an individual investigation site or entirely at any time. Suspension or early termination of an investigation site may occur due to serious

or repeated noncompliance on the part of an Investigator. Reasons for suspension or early termination of the entire study may include, but are not limited to, the following:

- The incidence and seriousness of AEs in this or other studies indicates a potential health hazard to subjects;
- New information on efficacy from this or other studies;
- The investigational product receives regulatory approval.

Subjects' may continue to use the new software if they consent to the extended follow-up, otherwise devices will be reverted to the commercially approved software version upon study exit. Once regulatory approval of the APM software occurs, the subject will be able to exit the study after the approved version is confirmed. After study exit, they will be followed by their physician in accordance with established practice for SCS systems.

13.12 Record Retention

The Investigator and Sponsor shall maintain the required records during the investigation and for a period of two years after the latter of either the completion/termination of the study or the date the Evoke System receives regulatory approval for the investigational programming software (i.e., APM) being studied. An Investigator or Sponsor may withdraw from the responsibility to maintain records for the period required and transfer custody of the records to any other person who will accept responsibility for them.

The Investigator's study records may be discarded only upon approval from the Sponsor. The PI must contact the Sponsor before destroying any records pertaining to the study to ensure that they no longer need to be retained.

13.13 Clinical Trials Registry/Database (ClinicalTrials.gov)

This clinical study will be registered on www.ClinicalTrials.gov. Study results will be submitted as required. Per the requirements of 21 CFR Part 50, the ICF will contain a statement that clinical trial information will be entered into this clinical trials registry/database.

13.14 Publication

Publication of clinical data from this trial will be in accordance with the fully executed CTAs. Publication of all data will conform to standards set forth in peer-reviewed journals and the Uniform Requirements for Manuscripts Submitted to Biomedical Journals published by the International Committee of Medical Journal Editors (ICMJE).

REVISION HISTORY

Revision	Description
06Jul2023	Initial release
05Jan2024	Added extended follow-up phase

ABBREVIATIONS AND ACRONYMS

Abbreviation/Acronym	Term
AE	Adverse Event
APM	Assisted Programming Module
CE	Clinical Equivalence
CFR	Code of Federal Regulations
CLS	Closed Loop Stimulator
CPA	Clarity™ Programming Application
CTA	Clinical Trial Agreement
CV	Curriculum Vitae
ECAP	Evoked Compound Action Potential
eCLS	External Closed Loop Stimulator
EDC	Electronic Data Capture
FDA	Food and Drug Administration
FCE	Field Clinical Engineer
GCP	Good Clinical Practice (For the purposes of this study, this means compliance with FDA regulations for IDEs and ISO 14155.)
GEE	Generalized Estimating Equation
HIPAA	Health Insurance Portability Accountability Act
IA	Investigator Agreement
ICF	Informed Consent Form
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IFU	Instructions for Use
IRB	Institutional Review Board
NSR	Non Significant Risk
PI	Principal Investigator
SAE	Serious Adverse Event
SCS	Spinal Cord Stimulator, or Spinal Cord Stimulation
SOC	Standard of Care
UADE	Unanticipated Adverse Device Effect
US	United States

BIBLIOGRAPHY

1. Russo M, Brooker C, Cousins MJ, Taylor N, Boesel T, Sullivan R, et al. Sustained Long-Term Outcomes With Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study. *Neurosurgery* [Internet]. 2020 Feb 5 [cited 2020 Feb 6]; Available from: <https://academic.oup.com/neurosurgery/advance-article/doi/10.1093/neuros/nyaa003/5727863>
2. Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, et al. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. *Lancet Neurol*. 2020 Feb 1;19(2):123–34.

APPENDIX A: SAMPLE INFORMED CONSENT TEMPLATE**RESEARCH SUBJECT INFORMATION AND CONSENT FORM**

TITLE: **Rosella APM Study:** A prospective, multicenter, single-arm study examining the Assisted Programming Module (APM) in the Evoke Spinal Cord Stimulation (SCS) System to program patients with chronic pain of the trunk and/or limbs.

PROTOCOL NO.: D103684

SPONSOR: Saluda Medical Americas, Inc.

INVESTIGATOR: Name
Address
City, State, Zip Code
Country

**STUDY-RELATED
PHONE NUMBER(S):** Phone Number
Phone Number(s) (24 hours)
[24 hour number is required]

INTRODUCTION

You are being asked to be in a research study because you have been, or are scheduled to be treated with, an Evoke spinal cord stimulation (SCS) system for chronic pain of your trunk and/or limbs. This study will assess modifications in the way the closed loop system is programmed. The purpose of this consent form is to help you decide if you want to be in the research study.

You may take home an unsigned copy of this consent form to think about or discuss with family and friends before making your decision. You are free to ask questions about this study at any time. You should not join this research study until all of your questions are answered. If you agree to take part in this study, you will be asked to sign this consent form. After you sign the form, you will be given a copy. An additional copy will remain in your medical chart.

Before you learn about the study, it is important that you know the following:

- Your participation is entirely your choice.
- You may or may not benefit from taking part in this study, but knowledge gained from your participation may help others.
- You may decide not to take part or to stop being in the study at any time without penalty or loss of benefits to which you are otherwise entitled.
- Parts of this study will involve standard medical care. Standard care is the treatment normally given for a certain condition or illness. Standard care would normally be provided to you even if you were not participating in the study.
- Other parts of this study may involve experimental (investigational) procedures that are being tested for a certain condition or illness. Experimental (investigational) procedures would not normally be performed as part of standard medical care.
- A description of this clinical trial will be available on [http:// www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This study is sponsored by Saluda Medical, a company that has FDA approval for the Evoke System for the treatment of chronic pain. The Evoke SCS you are planning to have or have has already been approved for use by the FDA and is not part of this study. This study is assessing an update to the programming software on the Evoke System to see if there are any benefits in the way the stimulation is programmed. The programming software has not been approved by the U.S. Food & Drug Administration (FDA). If you have any questions, please ask.

PURPOSE OF THE STUDY

The purpose of this research is to investigate a new programming software module, called the Assisted Programming Module (APM) in patients who already have the Evoke System. The APM is an optional assisted programming workflow that guides the operator through the same steps that would be performed manually during a programming session.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

Your active participation in the study does not occur until you have the Evoke SCS trial stimulator placed. The Evoke SCS that you have had implanted or are planning to have implanted is approved for use by the FDA and is not part of this study. This study is only assessing a new programming application.

As part of standard care when a spinal cord stimulator is placed, is that your device is programmed according to your individual pain condition. Your stimulator will be programmed by a Sponsor representative with the oversight of the study doctor. The study doctor will decide what programming is right for you based on how well the stimulator is controlling your pain.

During the trial stimulation phase, you may return to the clinic as often as needed to get the stimulator reprogrammed. For this study, you will not have any additional required visits in the trial phase, only visits to optimize the programming (as needed).

The programming session includes time for the clinical representative (FCE) to upgrade the device to the new software version and then program your system. You will be asked to change postures (e.g., head back, head forward, sit, stand, lie down, cough, walk), questions about usability (stimulation sensation, stimulation intensity, stimulation location while programming parameters are modified and/or while you move into different postures). This session will be very similar to a standard of care programming session from your perspective with the exception of additional questions that are asked about the programming session, which may increase the visit time by up to 30 minutes.

If you proceed to the permanently implanted SCS system, the same programming sessions will occur as needed to optimize your therapy. The programming sessions will take up to an hour.

You may come into the clinic at any time should your study device need reprogramming to better provide therapy.

After the programming visits, the Sponsor representatives will contact you by phone (or text message) to determine if the stimulation program is functioning as expected. Based on this contact, additional training or troubleshooting may be provided. If you have any concerns about your stimulation, you may contact your clinic at any time. Depending on when the programming visits occur, it may be that the 1-month or 3-month visit will be completed in replacement of the telephone follow-up.

You will be required to come back to the clinic 1-month and 3-months after the permanent implant is programmed. These visits will take up to 1 hour and the following will occur:

- You will be asked questions about your pain, stimulation sensation, stimulation programs, satisfaction with the programming process
- Your study device system will be tested and the setting of the study device will be changed if it is needed.

HOW MANY PATIENTS WILL TAKE PART IN THIS STUDY?

Approximately 30 subjects are expected to participate in this study at up to 5 study sites in the United States.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will end after completion of the temporary trial SCS if you do not go on to get the permanently implanted system. If you are implanted with the permanent SCS system, your active participation in this study is expected to last 3 months after the permanent implant unless you consent to the extended follow-up phase. If you consent to the extended follow-up phase, there are no required study visits after the 3 month visit. If you require re-programming of your device that will be part of the study. Your re-programming will be part of the study until the time of FDA approval of the Investigational software, which may be up to 2 years after the 3 month visit. Your participation will end once the investigational software on your device is approved by FDA.

WHAT HAPPENS AT THE END OF THE STUDY?

If your participation ends early in the study for any reason or at the end of the study, the new software can be left in place (if approved by the US Food and Drug Administration (FDA)). If the software is not approved, you will have your software returned to the FDA approved version. You should discuss these options with your doctor to determine which one is best for you. At the end of your study participation, you will continue to receive standard of care follow up with your doctor.

WHAT ARE THE RISKS OR SIDE EFFECTS OF THIS STUDY?

Saluda Medical has reviewed the new programming software that is being trialed in this study and has concluded that the overall residual risk for the Evoke System remains unchanged from what has been commercially approved.

However, it is possible that side effects may be experienced during the study and we will be monitoring these carefully.

If new risks are identified you will be advised immediately.

The trial and implant procedures and implant itself are not part of this study so you will be advised about the implant procedure risks separately from this informed consent. You will also consent to the procedure itself using the hospital standard consenting process and form.

ARE THERE ANY BENEFITS TO TAKING PART IN THIS STUDY?

You might not receive any benefit from being in this study. The new programming module may assist in improvements to how the clinical representative programs your device. The results of this study may help people being programmed in the future.

WILL I BE PAID TO BE IN THIS STUDY?

You will not be paid to be in this study. You will be reimbursed \$100 per study visit by the site for reasonable and modest expenses for transportation (e.g., parking, tolls, mileage). The three visits you will be reimbursed for include temporary trial programming (which typically occurs on the day of the trial procedure), 1-month and 3-month visits that occur post permanent implant procedure programming.

WHAT ARE THE COSTS TO ME?

The Evoke SCS trial and implant procedure and standard of care follow up is not part of this study. You or your insurance company will be billed for all tests and procedures that are required as part of your SCS. Saluda Medical will not cover the costs of these other medical tests or procedures not required by the Study.

You will not be charged for programming sessions that are only required for the study. Please ask your study doctor if you are unsure about whether a specific test or procedure will be billed to your insurance plan, to you, or will or will not be covered by Saluda Medical.

WHAT IF I AM INJURED OR BECOME ILL DURING THE STUDY?

If you get hurt or sick during the study, promptly seek help and contact the study doctor. The study doctor will treat you or arrange for your treatment, although you may seek treatment at any other convenient medical facility. The study sponsor, Saluda Medical, has agreed to pay for the reasonable and necessary medical costs for the short-term treatment of your injury or illness if your injury or illness is caused by the study device or by any properly performed procedures or testing required by the study.

The Sponsor has not agreed to pay for any injury or illness that occurs as a result of negligence, malpractice or other wrongful acts on the part of the study doctor or the study staff. The Sponsor has not agreed to pay for any injuries or illnesses that are the result of a pre-existing condition or the normal progression of your disease, because you have not followed the directions of the study doctor, or any other reason.

The Sponsor has not agreed to pay for any other costs, including pain, worry, lost income, or non-medical care costs that occur from taking part in the study.

You are not giving up any of your legal rights by signing this consent form.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

You do not have to participate in this research study to be treated for your pain. You may continue to receive the Evoke SCS System and be programmed with the current programming method. You should discuss with your study doctor in order to pick the best option for you.

WHAT IS THE ROLE OF THE SPONSOR'S REPRESENTATIVE?

As part of this study, a representative of Saluda Medical may:

- Provide technical expertise on the study device system you will receive;
- Be present at the programming and at the follow up visits;
- Program your study device and collect your feedback during the programming and follow-up visits; and
- Have direct contact with you (e.g., in person, phone call, text message, email, etc.)

The study doctor or their designee will always be present or nearby.

You can ask Saluda Medical representatives any questions about the study, however be aware that they may not be allowed to discuss certain aspects of the study with you. In particular, they are not allowed to make any promises or give information to a study subject that is different from any of the information in this form. If you think you have heard something that is different from the information in this form, please tell the study team as the information may be incorrect. If you have questions, please ask the study doctor or a member of the study team.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

As part of this study, your study doctor and surgical facility will keep records of your participation in the study. This section of the consent form describes how your personal information may be used and disclosed as part of the study. Under federal law, your personal information cannot be used or shared for the study by the Researchers (as described below) unless you sign this form. You do not have to sign this form. If you do not sign it, you will not be able to be in the study, but it will have no other effect on the medical care you receive.

What information about me can be used or shared in the study?

The personal information that may be used or shared is:

- All information collected during the study, including your birth date, treatment dates, device identifiers and other details about you, including contact information.
- Information in your medical records that is relevant to the study, including past medical records and the results obtained during the study.
- Videotapes, films or photographs of the trial stimulation phase and implant of the device. Reasonable effort will be made to not reveal your identity in the video or photos. If you agree, the Sponsor may ask to take videotapes, films or photographs of you discussing your SCS therapy.
- Records relating to your medical charges (your medical bills) regarding your treatment that are relevant to the study
- If the Sponsor pays for treatment of a research related injury or complication, you may be required to provide additional personal identification information (such as your social security number or health insurance claim number) and some of your personal health information to the Sponsor for the purposes of reporting such compensation to Medicare, Medicaid, or insurance companies.

When you see the phrase “personal information” in this form, it means all of this information.

Who can disclose my personal health information and who might receive it?

As part of the study, your personal information may be kept by the [facility name], [practice group name], [investigator name], and the people who work for them. The people who work with them include the Institutional Review Board, which is a group of people who watch over the study for the hospital or practice. It also includes other employees and contractors who need to see your personal information to help with the study or make sure it is being run right. Any of these people or groups of people may disclose your information. These people and groups are called the “Researchers” in this form.

People working with any of the following groups might receive your information:

- Saluda Medical, the Sponsor of the study, including its employees, contractors and representatives, as well as any company that later takes over or joins Saluda Medical as Sponsor of the study or that purchases the SCS System from Saluda Medical;
- The Institutional Review Board;
- Other institutions and laboratories that are participating in the study and their Institutional Review Boards;
- Government organizations such as the Food and Drug Administration (FDA), Office of Human Research Protections and similar agencies in other countries and other persons (such as the Data Safety Monitoring Committee) have the right to see your information required to watch over the safety, effectiveness, and conduct of research.

How can my personal health information be used?

Information about you can be used and disclosed (shared) by the Researchers and Sponsor for any of the following reasons:

- To monitor and/or audit the study and to confirm the research results;

- To contact you during the course of the study;
- To prepare publications or presentations (but no publication about the study will reveal your identity without a different specific, written permission from you);
- For regulatory purposes, such as meeting the reporting requirements of government agencies and getting the approval of government agencies to sell products made by the Sponsor;
- To create a data set from which all personal information that could be used to identify subjects has been removed;
- To support the marketing, distribution, sale and use of the study device;
- To conduct new medical research and other activities related to research and development of new medical products or therapies;
- For reimbursement purposes, that is to decide how the device and procedure that is the subject of the study will be paid for by Medicare, Medicaid, or insurance companies;
- As required by applicable laws.

Can I take back (revoke) my signature on this form?

Yes. You can change your mind about allowing your personal information to be used or shared at any time by sending a written notice to your study doctor. If you change your mind, you will be taken out of the study and no personal information about you will be gathered for the study after that date, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of the research.

Is my personal information always protected?

After the Researchers have shared your personal information with third parties, including the Sponsor, federal laws may not protect it from being further shared.

Can I see my personal information?

You will not have access to personal information related to this research study until the study is done. This information is available to your doctor in the case of an emergency. At the end of the study, you will again have access to personal information that is normally within your medical records. However, some research records will not be part of your medical record and you may not be allowed to see those research records. There may be other limitations on access to medical information unrelated to this study.

Does this form have an expiration (end) date?

The Researchers may use and share your information until the study and any necessary follow-up activities for the study have been finished. There is no end date for when the Sponsor can use your personal information.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

Your participation in this study is entirely your choice. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. If you withdraw from the study, you are asked to notify the study doctor so that your future care can be discussed and your participation can be stopped in a safe and orderly manner.

You will be told about any new findings about the device or this study, or if any changes are made to the study plan that may make you change your mind about staying in the study.

Your participation in this study may be stopped at any time by the study doctor or the Sponsor without your consent for any reason, such as:

- if it is in your best interest,
- if you need additional treatments,
- if you do not follow the study instructions,
- your medical condition changes,
- the study doctor feels it is in your best interest to stop the study,
- if you do not consent to continue in the study after being told of changes in the research that may affect you,
- decisions made in the Sponsor's judgement, or
- for administrative reasons.

SOURCE OF FUNDING FOR THE STUDY

This clinical research study is paid for by the Sponsor, Saluda Medical, who makes the device being tested. The study site is being paid by the Sponsor for their time, staff and facilities required to conduct the study. Research monies may help support the research and educational programs of the clinical site, including salaries of the study doctors and study nurses who conduct the study. [as applicable, add a statement of the Investigators' financial compensation]

QUESTIONS

Contact [name] at [number(s)] for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury or a reaction to the study device, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may also contact:

[IRB Name]
[Address]
[Telephone]
[E-mail]

An IRB is a group of people who independently review research.

An IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact the IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another has the right to:

- (a) Be informed of the nature and purpose of the experiment.
- (b) Be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be used.
- (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment, if applicable.

- (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment if applicable.
- (e) Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
- (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment or if complications should arise.
- (g) Be given an opportunity to ask any questions concerning the experiment or other procedures involved.
- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue in the medical experiment without prejudice.
- (i) Be given a copy of a signed and dated written informed consent form when one is required.
- (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

CONSENT

My signature on this consent form means that I have read and understand the information in this form about the study and willingly agree to participate in this study. My signature also means that my study doctor or their designee has talked with me about the study and I have had a chance to ask questions to my satisfaction. I know that taking part in this research study is my choice and that I can quit at any time. If I decide not to take part in the study, it will not affect my medical care outside of the study in any way. By signing this consent form, I also agree to let [institution] use and share my personal information to the entities and for the purposes as explained above in the section entitled "Authorization To Use And Disclose Information For Research Purposes". I do not give up any of my legal rights by signing this form.

Signature of Subject

Date

Printed Name of Subject

Signature of Consenting Investigator or Designee

Date

Printed Name of Consenting Investigator or Designee