PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Study Title:	BASMATI - Basic Assessment of Safety and Minimally invAsive sTimulation via Injectrode
Short Title:	Neuronoff Basmati Injectrode
Protocol No.:	NCP-01
Sponsor:	**Neuronoff, Inc.** 11000 Cedar Rd, Ste 290 Cleveland, OH 44146
Sponsor Contact:	Shaher Ahmad Shaher@neuronoff.com 269-903-5499
Investigator:	Amol Soin, MD 7076 Corporate Way Dayton, OH 45458 Tel: 937-760-7246 drsoin@gmail.com
Site:	The Ohio Pain Clinic 7076 Corporate Way Dayton, OH 45458 Tel: 937-434-2226
Daytime Tel#:	Tel: 937-434-2226
24-Hr. Contact Tel#:	Tel: 937-434-2226

CONFLICT OF INTEREST DISCLOSURE:

Dr. Soin serves as a consultant and shareholder of the Neuronoff, Inc. that makes the Injectrode device

used in this study. These financial interests are within permissible limits.

Introduction

Informed Consent

A person who takes part in a research study is called a research subject or study subject. In this consent form "you" always refers to the research subject. By reading this informed consent, you are being asked to give your authorization to participate in clinical testing/trial sponsored by Neuronoff, Inc. to evaluate the safety of the short term placement of the Basmati Injectrode for up to 28 days and efficacy of conducting electrical current and stimulating subcutaneous nerves on the explant date right prior to explant.

This consent form contains important information, which will help you to decide if you wish to participate in the clinical testing/trial. Take time to ask the study doctor or study staff as many questions about the study as you would like. If you decide to take part in this study, you must sign your name at the end of this form and date. You cannot take part in this research study until you sign and date this form. You will be given a signed and dated copy of this informed consent form to keep.

IT IS IMPORTANT THAT YOU READ THE FOLLOWING INFORMATION AND ASK AS MANY QUESTIONS AS YOU NEED TO UNDERSTAND WHAT YOUR PARTICIPATION WILL INVOLVE.

This informed consent form describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. Reading this form and talking to the study doctor and/or the study staff may help you decide whether to take part or not. You should be clear that this study is ONLY an experimental study. You can ask questions now or any time during the study. You have the right to withdraw from the study at any time. If you do not want to be in the study, your doctor will continue to treat you under standard of care. If you decide to quit the study, you will not lose any medical benefits. Taking part in this study is entirely voluntary.

PURPOSE OF THE RESEARCH

The purpose of this clinical study is to evaluate the safety and efficacy of the short-term placement of the Neuronoff, Inc. Injectrode for up to 28 days, then to conduct electrical stimulation of the nerves under your skin on the date before removal of the device.

PROCEDURES

The following schedule shows the events and tests that you will have to do at each of the targeted 10 subjects' follow up time point. A checkmark indicates the time-point when a particular test is requested.

Schedule of Events (SOE)

Assessments and Data Collection	Screening and Enrollment	Call for patch removal	Injectrode Placement	Follow-up visits	Efficacy and Explant visit	Post study follow-up
Day (relative vs. Placement)	-5 to -4	-2	0	7 ± 2 14 ± 2	28 (-2 to 0)	48 ± 2
● Eligibility confirmation	✓					
● Medical history ● Physical exam	✓ ✓					
● Informed consent	✓					
● Record demographics ● Verification of absence of allergy to gold & pregnancy test ● Confirmation of study eligibility	✓ ✓ ✓					
● Gold skin patch test placement	✓					
● Removal of skin patch		✓				
● Read skin test patch results			✓			
● Basmati placement procedure ● Ultrasound & Fluoroscopy image capture			✓ ✓		✓ (pre+ post)	(✓)
● Capture of images of surgical site ● Remove skin suture(s) if placed during surgery	✓		✓ (post)	✓ (✓)	✓	✓ (✓)
● Measure impedance needle to needle connection ● Measure stimulation thresholds ● Removal procedure ● Study participant exit					✓ ✓ ✓	✓

Table 1: Assessments and data collection

What is involved if you decide to take part in this research study?

- Prior to the procedure you will be examined by your physician to determine if you have any clinical signs or symptoms that may interfere with or inhibit testing within this study. To determine if a participant is showing any clinical signs or symptoms that may interfere with or inhibit testing of the condition under this study.
- Concomitant medications
- Medical history: To determine if there are any clinically significant diseases or medical conditions/procedures that may interfere with or inhibit this study.
- Any potential adverse events will be also evaluated
- During the surgical procedure, the Basmati Injectrode is ejected from the delivery device after introducing the cannula into a subcutaneous tunnel made by the clinician. The process can be

achieved in under 10 minutes of surgical time.

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for approximately 50 days after your enrollment, with a maximum insert placement time of only 28 days. During this time period, you will be treated and closely monitored.

STATEMENTS OF CONFIDENTIALITY AND PRIVACY

Records of your participation in this study and other documents concerning your medical records will be held confidential and be governed by laws such as HIPAA. However, there are always some risks that are associated with your privacy when you are asked to share your information. You will be assigned a unique code number when participating in this study. All information about you that is collected will be linked to this number and stored on password protected computers/electronic devices. The key to the code will be kept in a locked file in the Neuronoff, Inc. office and at this hospital site. By signing this consent, you are authorizing investigator(s), the sponsor or persons working on behalf of the sponsor, the United States Food and Drug Administration (FDA), the Institutional Review Board (IRB), the Department of Health and Human Services (DHHS) and other government agencies will be able to access, inspect, and copy confidential study-related records that identify you by name. This means that absolute confidentiality cannot be guaranteed. The office of physician staff may use your information to notify you of appointments, send you appointment reminders or schedule additional appointments. If the results of this study are published or presented at meetings, you will not be identified.

RISKS AND DISCOMFORTS

There are always some risks and discomforts associated with clinical trial studies. The most common may include:

Allergic Reaction(s)
Neuronoff Basmati Injectrode may cause possible allergic reactions. Some symptoms of allergic reactions are: skin rash, fast pulse, sweating, tingling and swelling of the eyes, face, lips, tongue, throat and/or vocal cords, sudden drop in blood pressure, difficulty breathing, loss of consciousness and/or associated with seizures, including the possibility of death if the allergic reactions are very serious or have not been treated on time. If you experience any of the above listed reactions, you should report it immediately to your physician and go to the closest Emergency Room.

Needles Insertion for electrical stimulation
Just prior to removing the device, two electro-acupuncture needles will be placed approximately 5mm into the skin covering the placed Injectrode, thereby forming an electrical interface with it. We will stimulate nerves beneath the skin and measure electrical signals. You may momentarily feel itch, tingle or pain.

This study is designed to facilitate a larger study in the future.

Unknown Risks
There are risks involved in all research studies. In addition to standard risk associated with medical devices like biocompatibility, sterility, infections or negative immune response, , there may be

uncommon or previously unknown risks that might occur. You will be notified of any significant new findings that become known, and you should report any problems to the research team members.

BENEFITS

There is a clinical need for a simple neuromodulation device that will provide electrical stimulation or impulses to certain nerves in order to block pain.

The Injectrode is a mesh formed from gold wire of 99.99% purity, designed to be inside human tissues while minimizing the risk of an unexpected reaction by the body. The Injectrode has dimensions of 2 mm by 4 mm by 10 mm, about the size of a typical grain of basmati rice.

ALTERNATIVES

Your participation in this study is completely voluntary and not mandatory. Your refusal to participate will not affect your medical care at any medical facility and/or with any medical professional.

COSTS AND PAYMENT TO PARTICIPANTS

Neuronoff, Inc.is covering all costs in this study relating to medical care and laboratory testing. All tests and procedures related to your participation are research-related.

COMPENSATION FOR INJURY

If you suffer side effects, injuries, or illness related to the study, contact your study doctor. Your study doctor will provide medical care and advice during and after the study. Treatment for injuries may include, if necessary:

- Bandaging or treating procedures sites;
- Providing treatment for pain.

If, as a direct result of taking part in this study, you are injured and require medical care that would not usually be necessary for your condition, the sponsor will cover the medical expenses necessary to treat your injury. You must follow the directions of the study doctor to be eligible for this coverage. Neither the sponsor nor the study doctor has a program in place to provide other compensation in the event of an injury.

LEGAL RIGHTS

The above section does not restrict your right to seek legal assistance. You do not waive any legal rights by signing this consent form.

COMPENSATION for STUDY PARTICIPATION

Participants in this study will be eligible for compensation at certain checkpoints, according to this compensation plan:

Event	Compensation
Screening	**$50**
Insert Placement	**$250**
Insert Removal	**$250**
Any Follow-up	**$50**

Note: No payments will be made to you (the subject) beyond what is explicitly stated above.

VOLUNTARY PARTICIPATION/WITHDRAWAL

You are free to leave the study at any time for any reason. If you choose to leave the study prior to your study procedure, you will only need to notify the study doctor and provide a reason for not participating. If you choose to leave the study during your study procedure, the equipment will be removed and/or disconnected in a safe manner. The study doctor may ask your reason for leaving the study, and you may contact the study doctor if you feel you experience any adverse event afterward. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

The study doctor, a representative of the study doctor, the sponsor or the FDA (Food and Drug Administration) may take you out of the study without your consent at any time for the following reasons:

- You do not meet the study conditions;
- You don't follow the directions of the study;
- It appears to be medically harmful;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- You become pregnant;
- The study is stopped;
- Administrative reasons;
- Or for any other reason.

WHOM TO CONTACT ABOUT THIS STUDY

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk

to the research team at the phone number(s) listed above on the first page.

This research is being overseen by an Independent Review Board ("IRB").

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.
- You can contact the IRB IntegReview IRB at 512-326-3001 or at www.integreview.com

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form. You may also notify other healthcare providers (like your primary care doctor) that you are participating in a research study.

SIGNATURE AND CONSENT/PERMISSION TO BE IN THE RESEARCH

Before making the decision regarding enrollment in this research, you or an authorized representative should have:

- Discussed this study with the study doctor,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature and date below means that you have received this information, have asked the questions you may have had about the research and those questions have been adequately answered. You understand the purpose of the study, clinical research investigations, study procedures, risks, discomforts and potential side effects. If you have any further questions regarding this study, or in the event of a study-related injury, you will need to contact the appropriate person named above. Based on this information, you voluntarily agree and give permission (consent) to take part in this study. You will receive a copy of the signed and dated form to keep for future reference.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

The subject is unable to consent because:

_____

As an authorized representative, I consent for the subject (print name)

_____

Next of kin, legal guardian, or authorized representative:

_____

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent