

**Project Title: A Pilot Study Investigating the Post-Operative Analgesic Effect of NSS-2 BRIDGE device in**

**Subjects Undergoing Major Abdominal Oncologic Surgery: A Randomized, Double-Blind, Placebo**

**Controlled Trial**

**NCT03555266**

**Date: August 1, 2018**



# University of Pittsburgh

*Department of Anesthesiology*

## CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

**TITLE: A Randomized, Double-Blind, Placebo-Controlled Pilot Study Investigating the Post-Operative Analgesic Effect of NSS-2 BRIDGE Device in Subjects Undergoing Major Abdominal Oncologic Surgery**

**PRINCIPAL INVESTIGATOR:** Jacques Chelly, MD, PhD, MBA  
Professor of Anesthesiology  
UPMC Shadyside  
5230 Centre Avenue  
Pittsburgh, Pennsylvania 15232  
412.623.6904

**CO-INVESTIGATORS:** David Bartlett, MD  
Matthew Holtzman, MD  
James Pingpank, MD  
Mohammad Haroon Choudry, MD  
Amer Zureikat, MD

**SOURCE OF SUPPORT:** Shadyside Hospital Foundation Grant Proposal  
5230 Centre Avenue

### ***Why is this research being done?***

The opioid epidemic has warranted research into alternative methods of pain relief. What's more, the

adverse side effects of opioids such as post-operative nausea and vomiting, respiratory complications, weakening of the immune system, and constipation are less than ideal. Therefore, non-pharmacologic pain therapies pose a great benefit to surgical patients who may otherwise become susceptible to opioid addiction as well as the harmful side effects that result from taking these medications alone. For example, a pain therapy called Percutaneous Nerve Field Stimulation (PFNS) has been shown to be effective as a complementary method of pain management. Using this mechanism of therapy, we are exploring a specific FDA approved device, called the NSS-2 BRIDGE. It is a non-invasive, battery-operated device containing electrodes that attach to the ear. It works by directly inhibiting nerves in the brain that are responsible for the sensation of pain, thus providing pain relief. We are hoping that by incorporating this device into post-surgical pain management, patients will require less opioids, which will in turn reduce harmful side effects and the risk of addiction.

***Who is being asked to take part in this research study?***

You are being invited to participate in this research study because you will undergo major abdominal oncologic surgery. People being invited to participate must be over 18 years of age.

***What procedures will be performed for research purposes?***

Screening Procedures:

There are no specific screening tests or procedures for this research study. Your medical records will be examined by your anesthesiologist to determine your eligibility for the study.

Procedures:

If you qualify to take part in this research study, you will undergo the procedures listed below:

After you sign an informed consent form, you will be enrolled into the study. You will be randomized, or randomly assigned via a computer-generated number system, into either the control or intervention group. The control group will wear an inactive placebo NSS-2 BRIDGE device and will receive the hospital's standard of care intervention as indicated by the Enhanced Recovery After Surgery (ERAS) protocol, which consists of a multimodal pain management regimen. The intervention group will receive an active NSS-2 Bridge device, which will supplement the ERAS protocol. This study is double-blind, so neither you nor your doctors and nurses will know which device you receive.

The NSS-2 BRIDGE(both active and placebo device) will be applied to the ear in the post-operative setting (PACU). Other forms of analgesia (pain medication) will be permitted via the approved ERAS protocol. The device will be affixed in accordance with the following image:



If you no longer wish to participate in the study for any reason, you may withdraw at any time.

### Monitoring/Follow-up Procedures

*Comfort Level:* Comfort level while wearing the device will be assessed at 12, 24, 48, 72, 96, and 120 hours post-operatively.

*Narcotic Consumption:* Rescue analgesia (pain medication) may be offered. Opioid consumption will be measured in total and while in the PACU.

*Post-operative Nausea and Emesis survey:* nausea and vomiting will be evaluated by nausea score (0-10), along with frequency of vomiting and antiemetic drug (drug that is effective against vomiting and nausea) usage.

*Patient Satisfaction Survey:* On the day of your discharge, you will be asked to complete a survey indicating your overall satisfaction as well as satisfaction as it pertains to pain management. This will be measured using a numeric rating scale where 0 indicates the worst satisfaction while 10 indicates the best satisfaction. We will contact you 3 months post-operatively to again assess your satisfaction as well as your recovery status.

*Device Return:* If you should be discharged prior to 120 hours post-operatively, we ask that you remove the device at this time and send it back to the hospital. We will provide removal instructions as well as a pre-paid envelope for its return.

*Device Care:* The device is water-resistant but not water-proof. It will malfunction, but not harm you, should it be submerged with water. You may bathe and wash your hair with the device, but care should be taken not to get it wet. It has been recommended that holding a dry wash cloth or a small plastic cup over the ear while showering will be enough to protect the device. If the device should come partially unattached while you are at home, we ask that you remove it fully and return it to the hospital.

Once the device is placed you will be asked to perform a "pinch test" throughout the duration of your time wearing the device. To perform the "pinch test" you must pinch down on the electrodes and ground to ensure they are still placed in their designated locations and have not come loose.

### ***What are the possible risks, side effects, and discomforts of this research study?***

There are risks associated with your surgery, anesthesia, and hospitalization. These risks will be discussed with you by your surgeon and anesthesiologist and are independent of your participation in this research study.

*NSS-2 BRIDGE Device:* This device may be associated with the risk of skin irritation and bleeding at the

application site. The investigator applying the device will have had the appropriate training to avoid these risks. For these reasons, patients with a history of hemophilia or skin conditions around the ear will not be eligible for study.

Your medical record will be accessed by study team. Some of the information reviewed in the medical record include medical history, surgical and anesthesia record, medication record and pain scores. All of your medical record and study-related information will be considered protected health information and will be kept confidential per HIPAA privacy act. There is, however, a possibility of breach of confidentiality. That is, in very rare cases, people not associated with this research study may inadvertently see your identifiable research results. We will do everything in our power to prevent this from happening by keeping all research records in locked files and identify all specimens and medical information by a research record number, rather than by your name or social security number. The codebook containing your name and number will be kept secure by the Study Team.

You can speak with your anesthesiologist if you have any questions or concerns regarding the implications and frequencies of each risk.

***What are possible benefits from taking part in this study?***

You may benefit by requiring fewer post-operative narcotics which may result in fewer opioid-related side effects.

***What treatments or procedures are available if I decide not to take part in this research study?***

If you decide not to take part in this research study, you will receive the standard of care anesthesia and post-operative care dictated by ERAS protocol.

***If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?***

You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

***Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?***

Some of the services you will receive during this study are “research only services” that are being done only because you are in the study. Examples are the Screening Procedures, Experimental Procedures, or Monitoring/ Follow-up Procedures described above. These services will be paid for by the study and will not be billed to your health insurance company or you.

The study is being paid for by the Shadyside Hospital Foundation Grant, the study device is being supplied via this means of support and you will not be billed for the device.

Some of the services you will receive during this study are considered to be “routine clinical services” that you would have even if you were not in the study. These services will be billed to your health insurance company or you, if you do not have health insurance.

You will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan.

You may want to get more detailed information about what “routine clinical services” your health insurance is likely to pay for. Talk to a member of the study staff and/or a UPMC financial counselor to get more information.

**Alternative treatments**

The NSS-2 Bridge is a device that is currently approved by the Food and Drug Administration (FDA) for use in pain management. It will be used in conjunction with the ERAS protocol. Even if you do not participate in this study, you will likely still participate in the ERAS protocol as it is the standard of post-operative care at UPMC facilities.

**Will I be paid if I take part in this research study?**

You will not receive any payment for participating in this research study.

**Who will pay if I am injured as a result of taking part in this study?**

University of Pittsburgh researchers and their associates who provide services at UPMC (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

**Who will know about my participation in this research study?**

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results. We will attempt to preserve your medical record and participation in this study as confidentially as possible, but breach of confidentiality is a risk of participation.

**Will this research study involve the use or disclosure of my identifiable medical information?**

This research study will involve the recording of past, current and/or future identifiable (pertaining to only you) medical information from your hospital and/or other health care provider (e.g. physician office) records. This information that will be recorded will be limited to diagnostic information, lab results, medications, and medical history. The information will be used to determine your eligibility for this study and to follow your care once you are enrolled in the study.

This research study will result in identifiable information that will be placed into your medical records held at UPMC and the UPMC Cancer Centers. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes response to study treatment including adverse events (side effects).

**Who will have access to identifiable information related to my participation in this research study?**

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance

Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

Authorized representatives of the study team, who are also part of the Department of Anesthesiology and the Acute Interventional Perioperative Pain Service, will review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

***For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?***

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for an indefinite period of time.

***May I have access to my medical information that results from my participation in this research study?***

In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider.

***Is my participation in this research study voluntary?***

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your anesthesiologist is involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your anesthesiologist.

***May I withdraw, at a future date, my consent for participation in this research study?***

You may withdraw, at any time, your consent for participation in this research study. Any identifiable

research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you decide to withdraw from study participation after you have received the study drug, no study assessments will be done after your withdrawal.

***If I agree to take part in this research study, can I be removed from the study without my consent?***

It is possible that you may be removed from the research study by the researchers if, for example, you have an unexpected change, complication in your anesthesia or surgery or serious adverse reaction to the NSS-2 BRIDGE device. If you are withdrawn from participation in this research study, you will still be treated for your post-surgical pain. Please consult your surgeon or anesthesiologist if you have any further concerns.

\*\*\*\*\*

**VOLUNTARY CONSENT**

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the principal investigator listed on the first page of this consent document at the telephone number given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study and to authorize Dr. Chelly and the members of his research team to access my medical records and extract research data from them, as described in this document. Dr. Jacques Chelly will sign this consent and a copy of this consent form will be given to me. Also, I further certify that no research component of this protocol was begun until after the consent form was signed.

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Date

**CERTIFICATION of INFORMED CONSENT**

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after

this consent form was signed.

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Role in Research Study

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date