

Study Title: A Pilot Study Investigating the nCAP Signal Relief Patch in Subjects Undergoing Primary Hip or Knee Replacement Surgery – A Pilot Trial

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IRB: STUDY22010018

NCT: 05252858

Informed Consent Form Approval Date: 08/25/2022



# University of Pittsburgh

*Department of Anesthesiology*

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

**TITLE: A Pilot Study Investigating the nCAP Signal Relief Patch in Subjects Undergoing Primary Hip or Knee Replacement Surgery: A Prospective, Randomized, Open Label Trial**

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**Source of Support:** nCAP Medical

### **Key Information:**

You are being asked to take part in a research study. Research studies are voluntary and only include people who are eligible and choose to take part. The study team members are available to you in order to explain the study and will answer any questions you might have. You should take your time and ask questions before you make a decision.

The purpose of this research trial is to study the effects of the nCAP Signal Relief Patch on post-surgical quality of life for individuals undergoing primary unilateral total hip or knee replacement surgery. An nCAP Signal Relief Patch is a negatively charged patch placed on the skin and is meant to redistribute the negative charges at the site of injury in order to reduce inflammation and pain. The nCAP Signal Relief Patch is not approved by the Food and Drug Administration (FDA) at this time.

We will ask you to participate for 30 days after your surgery where we will contact you on post-surgery days 1, 2, 3, 7, 14, and 30 to assess your recovery and pain levels.



Figure 1: nCAP Signal Relief Patch

This study is a randomized-controlled trial. Participants will be randomly assigned (like a flip of a coin) to one of two groups: the intervention group, where a nCAP Signal Relief Patch is administered post surgery, or the control group, where no patch will be administered. A picture of the nCAP Signal Relief Patch is provided here.

You may benefit from this study by potentially reducing post-operative pain and opioid consumption.

If you decide not to participate in this study, you will still receive the standard of care, which includes Shadyside Hospital's Enhanced Recovery After Surgery (ERAS) protocol during your hospital stay, which consists of a multimodal pain management regimen (a combination of various groups of medications to provide pain relief). This protocol is designed and used by your surgical team to ensure the best possible outcome from surgery and contributes to the type of care you receive before, during, and after the procedure.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may receive. You will not be notified of any results that might affect your personal health or decisions.

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

The opioid epidemic has warranted research into alternative, non-pharmacological methods to treat post-operative pain. Inflammation and pain post-surgery affect recovery. Therefore, we are testing the efficacy of the nCAP Signal Relief Patch to lower pain and lower opioid use.

The theory behind this study is that the nCAP Signal Relief Patch uses neuro-capacitive coupling technology, which redistributes the negative charges at the local level, providing an anti-inflammatory effect and a decrease in pain. The Patch uses this technology in order to bring drug-free relief for pain and discomfort. 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 have agreed to undergo a unilateral hip or knee replacement surgery.

People being invited to participate must be over 18 years of age.  
Sixty (60) subjects are planned to be enrolled in this research study.

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

### Screening Procedures:

Your medical records will be examined by your anesthesiologist to determine your eligibility for the study. If you are deemed eligible, and wish to participate in the study, you will be asked to complete a questionnaire regarding your mood. The results of this form will determine eligibility to participate in the study.

### Procedures:

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

You will be asked to complete three more questionnaires regarding your mood and experience with pain and sleep prior to surgery. After the surveys, we will conduct a functionality test to assess the mobility and strength in your leg prior to surgery. This will be assessed by observing your ability to walk 100 feet, go up 5 steps and raise your leg. Participants who are eligible will be randomly assigned (like a flip of a coin) to one of two groups: the intervention group, where an nCAP Signal Relief Patch will be applied after surgery, or the control group, where no Patch will be applied after surgery, acting as a control.

Regardless of which group you are randomized to, you will still follow the approved Enhanced Recovery After Surgery, which includes a multimodal pain regimen. The research team will still follow up with participants in both groups for 30 days.

Other forms of medications will be permitted during study participation. If you no longer wish to participate in the study for any reason, you may withdraw at any time.

We are also requesting your authorization or permission to review your medical records to determine whether you meet the conditions for participation in the study and to place this information in the research registry. We will obtain the following information: medical history, medication use, age, gender, allergies, and surgical record. This identifiable medical record information will be made available to members of the research team for an indefinite period of time. Your medical information may be shared with other groups as described above, and possibly including authorized officials from the University of Pittsburgh Internal Review Board, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues.

We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records once your personal information is disclosed to others outside UPMC or the University. This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in the study. Any information obtained from you up to that point will continue to be used by the research team.

### Monitoring/Follow-up Procedures

*Hospital Discharge:* At the time of hospital discharge, you will be given instructions on how to record pain medication and pain scores while at home. This will be done via email (REDCap Survey) that will be sent to

you. A REDCap survey is an electronic survey that will be sent to you via email and will provide instructions on how to record these assessments. We will record your pain medication and pain scores while you are in the hospital.

*nCAP Patch Removal:* Those in the intervention group will be treated with the nCAP Signal Relief Patch in the post-anesthesia care unit (PACU) after their surgery. Once the patch is placed, it should be left in place for 72 hours. At the end of the 72-hour period, you may remove it at home. However, it does not need to be disposed of as it is made of medical grade material and you can keep the patch to re-use for other pain in the future if you wish.

*Post-Operative Pain:* Level of pain at rest and with movement while wearing the patch will be assessed at 24, 48 and 72 hours post-operatively. This will be measured using a numeric rating scale where 0 indicates no pain and 10 indicates the worst pain imaginable. You will be contacted via electronic diary (REDCap) or by phone at days 7, 14, and 30 post-operative to again indicate your level of pain at that point in the recovery process.

*Pain Medication Consumption:* Rescue analgesia (pain medication) may be offered. Pain medication consumption will be measured in total at 24, 48, 72 hours and days 7, 14, and 30 postoperatively. You will be contacted via electronic diary (REDCap) or by phone to report this again at day 7, 14 and 30.

*Sleep Disturbance:* This survey will be completed prior to surgery and post-operatively on days 7, 14 and 30 via electronic diary (REDCap Survey) or by phone.

*Functional Recovery:* Functional recovery will be assessed by determining your ability to walk 100 feet, go up 5 steps and raise your leg on the day of your surgery, and on postoperative days 1, 2, 3, 7, 14 and 30. There will be specific directions in the electronic diary (REDCap) on how to report this or it will be reported over the phone.

*Overall Patient Satisfaction Score:* You will be asked to assess your overall patient satisfaction with the pain management, with 0 being least satisfied and 10 being most satisfied. You will be contacted via electronic diary (REDCap) or by phone on post-operative day 30.

Email surveys (REDCap) will not be initiated until after you have been discharged from the hospital. Prior to discharge, all assessments will be done by a research team member at your bedside.

If you do not have access to a computer, smart phone or email we will contact you via phone to complete these follow-up assessments. A research team member will contact you on the day of follow-up and will verbally complete each assessment over the phone. You will continue to be contacted post-operatively to gather your responses to the surveys a maximum of three times. If we are unable to reach you after three days you will be considered lost to follow up.

***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.

*nCAP Signal Relief Patch:* The patch is associated with an infrequent risk of skin irritation. To avoid this risk, the patch will be placed by trained research personnel on the surgical dressing and will never be placed on the skin or wound directly. You will be asked to report to the research team or your physician if you have any concerns regarding irritation from the patch.

*Questionnaire Administration:* Some individuals may find the questionnaires boring or tedious to answer.

*Breach of Confidentiality:* 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.

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

You may benefit by requiring fewer narcotics for effective pain management following surgery, which may result in fewer opioid 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 surgical, 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. This includes the nCAP Signal Relief Patch. These services will be paid for by the study and will not be billed to your health insurance company or you.

This study is being paid for by nCAP Medical. The patch is being supplied by this means of support and you will not be billed for it.

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.

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

You will receive \$50 for completion of the day 1 screening, \$25 for completing up to the 72 hour post-operation assessments, \$25 for completing the Day 7 follow-up, \$25 for completing the Day 14 follow-up, and \$25 for completing the day 30 follow-up. The total amount of compensation for this trial is \$150.

Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. If the total reimbursement for your participation in research is greater than \$600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

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

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is 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. Your insurance provider may be billed for the costs of this emergency treatment, but none of those 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. At this time, there is no plan for any additional financial compensation. You do not waive any 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. Although every reasonable effort has been taken, confidentiality during internet communication activities cannot be guaranteed, and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

***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 Office of Research Protections 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 University of Pittsburgh Institutional Review Board 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).

Authorized representatives of the U.S. Food and Drug Administration (FDA) may review your identifiable research information (which may include your identifiable medical information) related to your participation in this study for the purpose of monitoring the accuracy of the research data.

In the future, the investigators may decide to share data with other investigators both within or outside of this institution. If this were to occur, we would de-identify all of the information prior to sharing data in this way.

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.

Also, per University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project.

***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 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 acetaminophen. 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.

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**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. 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