Informed Consent Form

Title:	**Deep brain stimulation (DBS) in patients with refractory chronic neuropathic pain**
NCT Number:	**NCT03029884**
Document Date (IRB Approval Date):	**July 16, 2020**

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Deep brain stimulation (DBS) in patients with refractory chronic Pain

This is a medical research study. Your study doctors, Prasad Shirvalkar, MD, PhD, and Philip Starr, MD, PhD, or Edward Chang MD, from the UCSF Department of Neurological Surgery from the UCSF Department of Neurology will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctors.

You are being asked to take part in this study because other treatment options have not adequately treated your chronic pain. Another possible option to study and potentially relieve pain symptoms involves brain surgery. This type of surgery procedure is done with deep brain stimulation (DBS), which involves delivering small electrical impulses to areas in the brain that might relieve pain symptoms. The surgery devices in this study for pain are currently classified as investigational by the FDA, meaning it is approved to collect data regarding how effective the device might be and safety-related measures, but it is not approved as a treatment for pain.

Why is this study being done?

This study will measure activity in areas of your brain known to be involved in pain when you report being in pain and not in pain. The study will also investigate if stimulation of these areas can reduce pain symptoms. DBS of these brain regions is investigational and involves potential risks, as discussed further in the consent (see pages 10-13 of this document).

What are the funding sources and are there any disclosures?

This study is supported by a grant from the National Institutes of Health and was previously supported by the Department of Defense (Defense Advanced Research Projects Agency).

Drs. Shirvalkar, Starr, and Chang will not be receiving money from Medtronic Inc. during the course of this study. These disclosures are being made so that you can decide if this relationship will affect your willingness to participate in this study.

How many people will take part in this study?

About 10 people will take part in this study at UCSF.

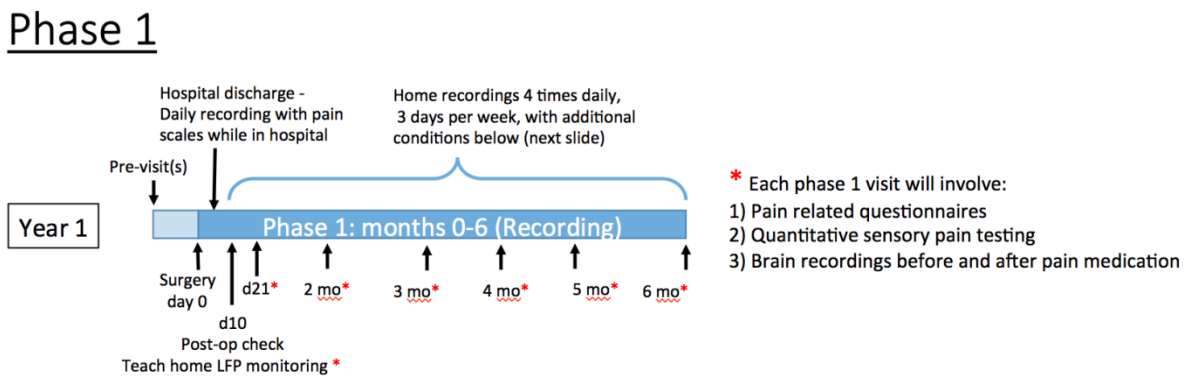
What will happen if I take part in this research study?

Before you begin the main part of the study...

If you agree to participate, you will be asked to sign the informed consent form before enrolling in the study. You will be asked to consent to testing including medical screening, an evaluation of your neurological abilities, medical and psychiatric history, and brain scans (magnetic resonance imaging (MRI) and computerized tomography (CT)).

There is a "screening" process associated with this study (see **Figure 1: Pre-visit(s)**). You will be asked to sign this informed consent form before being enrolled in this study.

Figure 1



Prior to the start of the study, we will describe the study to you on the phone briefly and then schedule an **outpatient pre-surgery visit or visits (Figure 1, Pre-study visit(s))**, where we will describe the study in detail and answer all of your questions. We will also have you fill out questionnaires that ask you about your mood, general health, memory functioning and pain states.

The research team may consult with your regular pain treatment team during the prescreening time. Prior to surgery, there may also be a physical exam to measure your clinical pain condition and symptoms. We may also schedule brain scans (MRI and/or computerized tomography (CT) to take pictures of your brain which will allow us to plan for brain surgery.

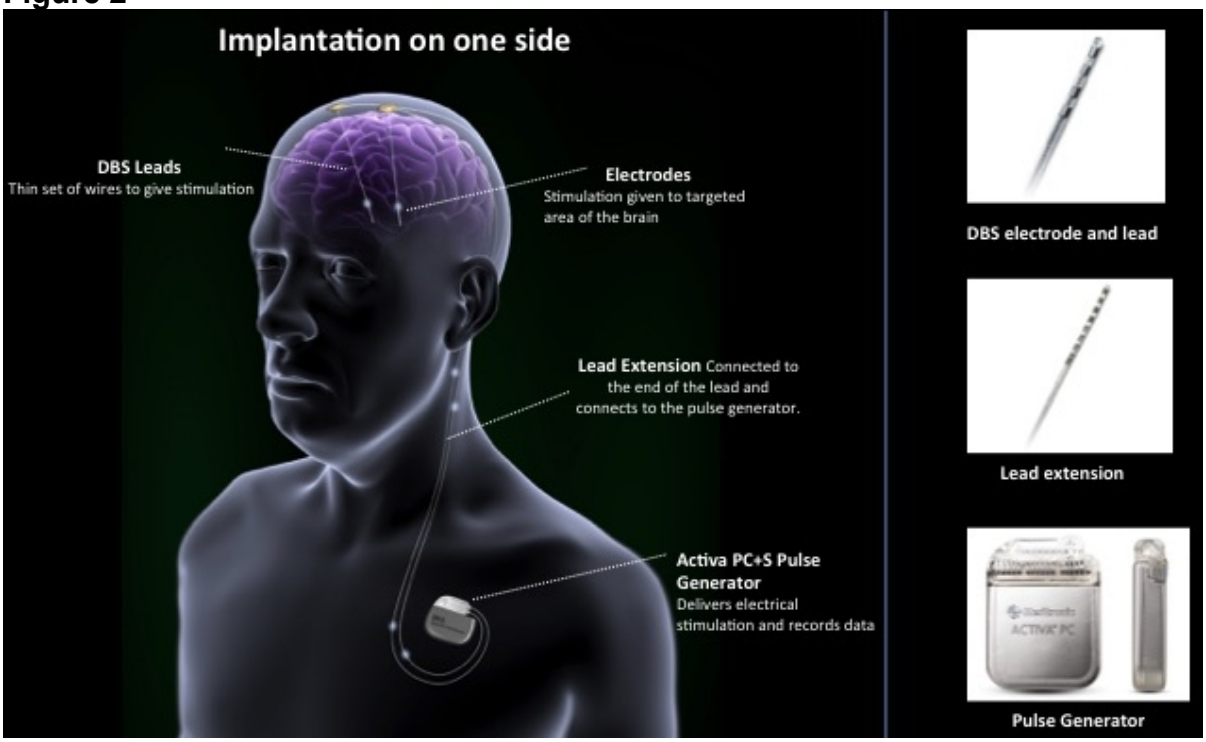
During DBS surgery…

Following the pre-study visit(s), we will schedule hospital admission for the brain surgery (see **Figure 1, Surgery-Day 0**). Before surgery, we will check that your health

status has not changed in ways that would make you not eligible for the surgery or the study.

In this brain surgery, two to four small devices made of platinum (1 to 2 inches long and 0.05 to 0.3 inches wide) called electrodes will be placed in certain regions of your brain (see **Figure 2**).

Figure 2



These electrodes record brain activity in the brain areas that they are placed. The electrodes can also deliver small pulses of electrical stimulation when programmed by the physician to do so.

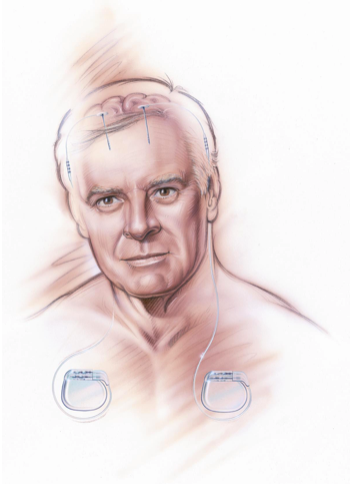
The electrodes are attached to DBS “leads”, which the surgeon will place through small holes drilled into the skull (burr holes). The DBS “leads” may also be placed in or on regions of the brain by craniotomy (temporarily removing the bone flap in the skull to better access the brain). The DBS leads are attached to “lead extensions” and the “lead extensions” attach to a “pulse generator” called Activa PC+S, which can deliver electrical stimulation and also store recorded brain activity. The Activa PC+S is implanted in the upper chest.

The devices used in this study are FDA-approved to treat Parkinson’s disease, but are only approved as “investigational” for chronic pain.

In this study, different regions in the brain related to pain are being studied. The regions implanted will be done in consultation with the surgeon and pain treatment team and these areas may vary across patients who participate in the study.

Depending on your pain symptoms, you may have one side of the brain implanted with two DBS leads / electrodes / lead extensions and one Activa PC+S in one side of the chest (unilateral implantation, see **Figure 2** for an example), or both sides of the brain implanted with two DBS leads / electrodes / lead extensions on each side, for a total of 4 DBS leads / electrodes / lead extensions and two Activa PC+S, one Activa PC+S on each side of the chest, (bilateral implantation, see **Figure 3** for an example).

Figure 3



After the electrodes are placed, **you will then undergo a head CT in the operating room to make sure the electrodes are in place.**

After DBS surgery…

After DBS surgery is completed, and while you are recovering in the hospital, the Activa PC+S system will be tested and brain activity recordings will be performed daily in the hospital (see **Figure 1, Phase 1**). It is expected you will recover in the hospital for approximately 1 week or less.

You will take part in research sessions at the UCSF Medical Center at regular intervals (approximately every month) and also collect at-home brain recordings.

Approximately 10 days post-surgery, at wound and staple check, a data recording session will take place in an out-patient setting and questionnaires related to mood will be given (see **Figure 1, Phase 1**). The recordings and research sessions after surgery will be done on an out-patient basis at our clinic (monthly) and from your home (4 times daily, 3 days per week).

Phase 1 at-home brain recordings

We will teach you how to record brain recordings from your home at the first out-patient visit (See **Figure 1, Phase 1, day 10, Teach at-home monitoring**).

For at home recordings, you will be given a hand-held device, the "intercept patient programmer" that is not approved by the FDA for treatment, but is approved for "investigational use". You can use this programmer to begin brain recordings from the Activa PC+S while you are at home. (Only the recording function is accessible at home. There is no way for you to accidently stimulate or activate any region of the brain with the device).

Study staff will instruct you or a family member or friend on how to use the intercept patient programmer to take recordings at the following times:

Three times per week:

1. One-minute recordings at the following times:

    a) Immediately after waking up in the morning
    b) 30 mins post medication use
    c) afternoon between 1200 - 1400 pm
    d) immediately before bedtime

2. One minute of recording any time after taking pain medications.

Two times per week:

1. Three minutes of recording during and after activities that you have pre-identified as making your pain symptoms worse (e.g. using the bathroom, walking or climbing stairs).

During the at-home recording sessions, you will also take pain reports you take pain reports (pen and paper, or on an iPad) at home after these neural recordings take place. The iPad or paper and pen scale ask you to rate your pain intensity on a scale from 0 to 10, with 0 being no pain and 10 being the absolute worst pain you have experienced. We will also ask you to report how much the pain is bothering you, on a scale from 0 to 10, with 0 being not at all bothering you to 10 completely bothering you.

With your permission, study staff may arrange to go to your home to help you with initiating the data recordings. These data can be downloaded at your next clinic visit, or, with your permission, during a home visit by study staff.

To assist the study staff, you may also be provided with a portable tablet that allows you to wirelessly transfer the data that has been recorded on the Activa PC+S into the tablet for storage. You can use this tablet at-home. Only the downloading function is

accessible – there is no way for you to accidentally stimulate or activate any region of the brain with this tablet. Medtronic is not responsible for any loss of data due to patient use of the device, however, in the event there is any data loss, the study staff will work together with Medtronic to recover any lost data.

We will make sure you feel comfortable taking the recordings before you do them at home or will make arrangements to have someone come help you.

We will also ask you to wear an activity tracker (e.g. FitBit) and upload your data via a smart phone application using an anonymous account (i.e. no personal identifiers will be linked to the activity tracker account).

Phase 1: Out-patient appointments (Months 1-6)
In the first part of the study (**roughly study months 1-6)**, we will be studying how brain activity signals when you are in pain versus not in pain. In these out-patient clinic study sessions, you will fill out various questionnaires in addition to undergoing brain activity recording sessions. The recording sessions will be done at various times and under various conditions, including at rest, during quantitative sensory testing (QST) in which you will rate cold and heat sensation from no detection to irritating detection, during various activities, (such as standing or walking) and before and after pain medications.

During recordings, temporary flat electrodes may be placed on your scalp and your arm muscles. We may also use electroencephalography (EEG), where temporary flat electrodes are placed on your scalp to help us obtain more brain signal data; this is similar to getting an EKG (electrocardiogram). Brain recordings will typically last from 1 minute to 3 minutes under the various conditions noted above. After brain activity recordings, the stored data will be transmitted from your Activa PC+S system to a research computer using a wand held over your chest, while you are sitting or lying down.

Your pain levels will be measured during the research sessions by standardized pain scales on an iPad, verbal report or pen and paper, by asking “On a scale of 1 to 10, how intense are your pain symptoms right now?” as well as “On a scale of 1 to 10, how much is your pain interfering with or bothering you right now?”

Each patient’s needs will be different and we will work with you to minimize discomfort as much as possible. You may also have friends or family accompany you at these sessions, if it would be helpful. Each research session will last approximately 2-3 hours.

CT Scan (Phase 1, ~ 2 months)
In addition to research sessions, approximately two months after brain surgery, you will have a computed tomography (CT) scan of your head done in order to check that the devices are in place. A CT scan uses special x-ray equipment to make detailed pictures of body tissues and organs.

For the CT scan, you will need to lie still on a table with your head inside a large

doughnut-shaped machine. The table will move and the machine will make clicking and whirring noises as the pictures are taken. Each CT scan will take about 15 minutes to a half hour. (See **Radiation Risks** in **What side effects or risks can I expect from being in the study?** in the section below.)

The research sessions and at-home sessions from Phase 1 of the study will allow us to potentially figure out how brain activity causes pain symptoms.

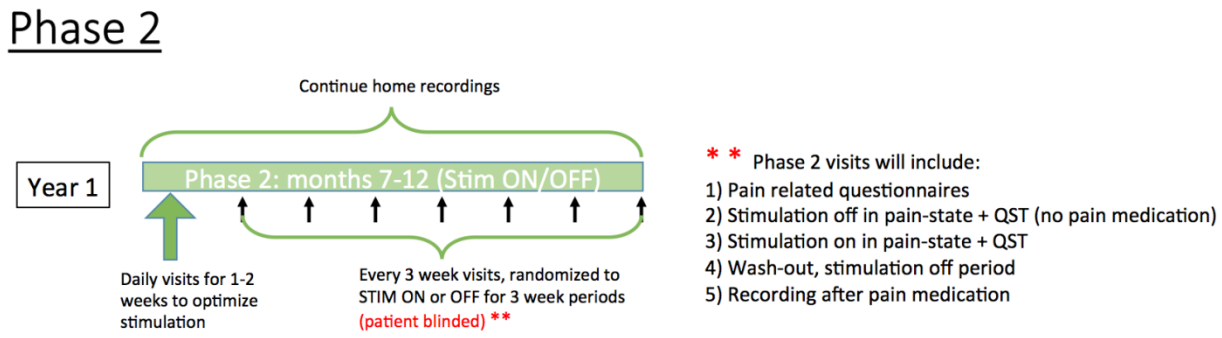
Based on the findings from phase 1, we will then stimulate the brain in response to pain-related brain activity in phase 2. We expect phase 1 to last approximately 6 months in order to discover a neural signature related to pain that may respond to neural stimulation. However, if enough data is collected before the 6-month time period and a potential neural signature is discovered earlier, you may start Phase 2 at an earlier time point. Likewise, if not enough data sessions are completed (at-home or in the clinic session), or if there is difficulty in detecting a biomarker or if a neural signature is not detected at the end of the 6-month time period, further neural data sessions, corresponding to either phase 1 or phase 2 may be needed.

Phase 2, Study Months 7-12:

The research sessions and at-home sessions from Phase 1 of the study will allow us to potentially figure out how brain activity causes pain symptoms.

Based on these findings, in phase 2 of the study (roughly study months 6-12, see Figure 5), we will then stimulate the brain, both in the clinic and at-home, in response to pain-related brain activity.

Figure 5



We will also be studying different stimulation settings in the outpatient research sessions that might lead to pain relief. We may also use electroencephalography (EEG), where temporary flat electrodes are placed on your scalp to help us obtain more brain signal data; this is similar to getting an EKG (electrocardiogram). To better detect brain

states that cause pain symptoms, you will continue to do the at-home data collection as in Phase 1.

At the beginning of Phase 2, we will conduct daily visits for the first 1 to 2 weeks to optimize the stimulation settings to potentially decrease pain states. We will then have you return to the clinic every three to four weeks to do in-clinic testing with stimulation, recordings, quantitative sensory testing with heat and cold sensations, cognitive attention testing using a computerized task, and/or administration of a pharmacological opioid blocker (Naloxone/Narcan) during these tests. To test for possible placebo effects, we will also activate or inactivate stimulation during the three-week time periods in between sessions. You will not know (i.e. will be blinded) to the active or inactivated stimulation. Your at-home brain recording sessions during this phase (see above) will also help us detect possible better stimulation patterns for disruption of pain states.

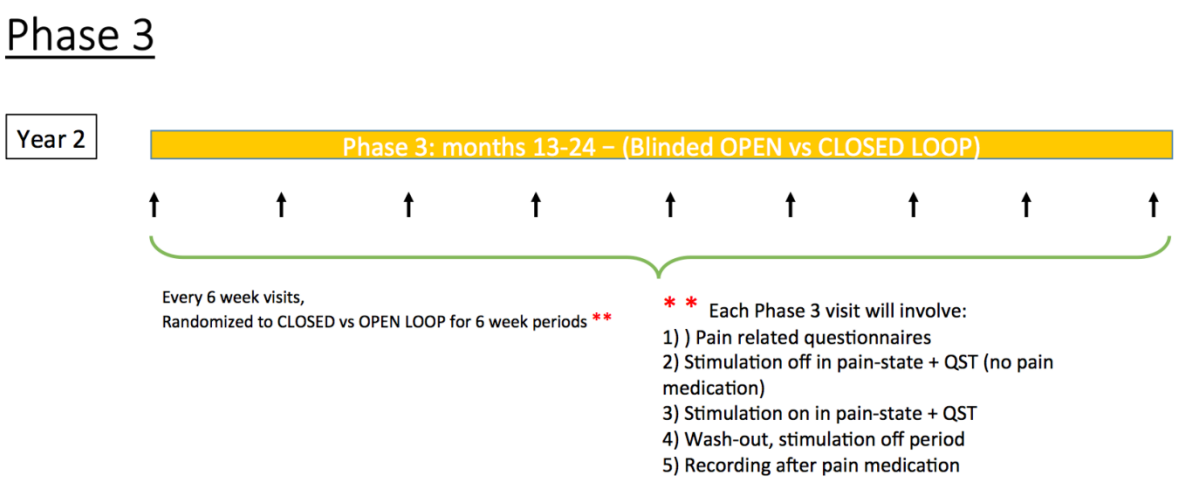
Phase 2 is expected to last 6 months (approximately months 7-12), but it may be possible for you to accelerate to the next phase sooner than the 6-month period, depending on various factors such as your response to stimulation, frequency of at-home recordings, etc. Likewise, Phase 2 may need to continue longer then 6 months. We will consult with you regarding length of phases depending on specifics for your individual symptoms.

Phase 3 (approximately months 13-24)

In phase 3 of the study (**see Figure 6**), we will set the brain stimulation settings to be always active in an at-home setting, with close monitoring by the medical and research team and frequent out-patient visits. We will be in touch with you daily by phone for the first 2 weeks after the stimulation is turned on and you are at home, and you will continue to report pain symptoms and pain relief during this time and wear an activity monitor, such as a FitBit.

We will also have you come to the clinic every 6 weeks, to check on your pain and possible pain relief. During this time, we will do additional testing in the clinic and may adjust stimulation settings.

Figure 6



Specifically, the brain stimulation settings will be either in a "responsive" mode (i.e. "Closed-loop" stimulation, in which stimulation will only occur depending on your neural activity that we have found in Phase 1 and 2 that predicts a pain state), or stimulation will take place in an "open-loop" manner, in which stimulation will occur regardless of neural activity status. "Open-loop" stimulation is stimulation that is currently in use in other medical studies and medical conditions, including treatment for pain. "Closed-loop" stimulation may differ in relieving pain symptoms than traditional "open-loop" stimulation, which we will test during this phase. You will be randomly assigned to one of these two modes ("open-loop" or "closed-loop" every six weeks) for year 2 of the study, months 13-24. Stimulation may also be turned OFF immediately after one of the two modes for up to 2-months to allow its effects to "wash-out" or fade before starting the next stimulation setting.

We will measure pain relief under these two conditions every six weeks, as well as pain related questionnaires, brain recordings under various conditions, quantitative sensory pain testing (heat and cold sensations), cognitive-attention testing, opioid blocker testing, and brain recordings before and after pain medications. We may also use electroencephalography (EEG), where temporary flat electrodes are placed on your scalp to help us obtain more brain signal data; this is similar to getting an EKG (electrocardiogram).

After the study is finished (roughly 2 years), and if it is possible to leave the device on and you choose the option to leave the device on, we will follow-up with you in additional appointments, approximately every 6 weeks.

How long will I be in the study?

Being in this study will take roughly over 2 years. The study will require 2 (or more) outpatient pre-surgery visits, hospitalization / surgery, daily in-hospital visits, and up to 37 outpatient post-surgery visits for a total of about 90-130 research hours, in addition to daily at-home brain data recording sessions (<1 hour per day, 4 days per week, for 1

year during Phase 1 and Phase 2). Outpatient visits, surgery and hospitalization will take place at the pain clinic at UCSF (either at Mission Bay or Parnassus locations). If you choose to continue having the device deliver stimulation after the study, we will have you come back to the clinic for follow-up visits (beyond the 37 outpatient study sessions) for check-ups, roughly every 6-8 weeks.

What happens to the study devices at the end of the study?
Your Activa PC+S pulse generator is expected to require surgical replacement after 2-4 years. When your pulse generator requires replacement, it may be replaced with Activa PC, the standard pulse generator model that delivers DBS therapy but has no ability to sense and store brain recordings, or another Activa PC+S depending on results from the clinical trial and in consultation with your regular pain doctor. These devices may provide a potential therapeutic stimulation strategy in continuing to treat your pain symptoms.

If you decide, in consultation with your doctor, to leave the device in or have it replaced, you will be monitored at the clinic for out-patient appointments, approximately every 6 weeks. Costs for replacement devices after the conclusion of your participation in the research study will be the responsibility of you or your insurance provider, depending on your insurance. You can also decide to have the device turned off or removed.

In the event that you develop symptoms that your doctors think are related to the study, such as muscle weakness or seizures, then your doctors may recommend surgical removal of the device and DBS electrodes.

Can I stop being in the study?
Yes. You can decide to stop at any time. Tell the study staff if you are thinking about stopping or decide to stop.

It is important to tell the study staff if you are thinking about stopping so that your doctor can evaluate any risks from the brain recording and discuss what alternative follow-up care and testing could be most helpful for you.

The study doctors may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?
You may have side effects while on the study, though brain activity recording is not expected to cause side effects. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to study staff about any side effects that you experience while taking part in the study.

Risks and side effects related to **DBS surgery** are estimates based on scientific literature to date, and may include:

Likely

- Temporary pain at the surgery sites
- Temporary headache after surgery
- Temporary increased pain states during some stimulation settings

Less Likely

- Seizures
- Infection in areas of the body in which the device comes into contact (i.e. brain, neck, chest) could lead to irritation or life-threatening illness which would require further surgery to remove all or parts of the device. Risks of removing the device may involve temporary pain at the surgery sites and temporary headache after surgery.
- Erosion of the device through the skin covering it, requiring further surgery to cover or remove the device
- Confusion or attention problems
- Muscle weakness around forehead that may interfere with keeping the eyes open and could lead to permanent weakness.

Rare but Serious

- Bleeding inside the brain (stroke), that could cause paralysis, coma, or death
- Harmful reaction to anesthetic agents
- Leaking of the fluid surrounding the brain
- Air embolism (air bubble that enters an exposed blood vessel on the surface of the brain or in the skull bone, which can travel to the heart and possibly lung, a potentially life-threatening condition).

Risks and side effects related to **implanted DBS electrodes**:

Likely

- A risk and side effect related to implantation of the DBS electrodes is that you should not have MRIs while the electrodes are implanted, and it will be important that you remember to inform any health care provider who is considering MRI that you have implanted DBS electrodes that makes MRI unsafe for you. Brain injury can occur from having MRI scans with an implanted stimulation system. Placement of two leads in one hemisphere is off-label (i.e. not recommended) for MRI. If you are in this study and require an MRI scan of the brain for important medical reasons, your doctors will determine if the reason for brain MRI is important enough to proceed. MRI scans are used to evaluate and diagnose a variety of symptoms and health problems, therefore you may experience a health problem that is harder to

diagnose because you should not have an MRI.

- You should also not undergo diathermy (high-frequency electrical current treatment, used often in treatment of arthritis) with implanted DBS electrodes and Activa PC+S pulse generators.

Less Likely
- None

Rare but Serious
- Possibility of damage to the brain from inserting a permanent electrode on the brain surface producing muscle weakness or seizures.

Risks and side effects related to brain activity recording are estimates based on scientific literature to date, and may include:

Likely
- Possible worsened pain symptoms after holding pain medications before some study visits, although the study will attempt to minimize altering medication schedules.

Less Likely

- If you have two pulse generators implanted instead of one, you may have a slightly increased risk of post-operative pain; infection due to an additional surgical site and an additional surgical scar. There is also potential for increased infection and pain associated with multiple leads (i.e. greater risk with 4 leads versus 2 leads).

- Possibility that the Activa PC+S generator will fail to deliver brain stimulation that will effectively treat pain symptoms. The Activa PC+S device contains the identical therapeutic stimulation components as those in the FDA approved device and would be expected to function with the same level of reliability; however additional sensing technology has been added, making the device experimental. Thus, as an experimental device, with additional sensing circuits that have not yet been approved for use in humans, there is a possibility that performance might not match the standard device. The actual risk of less effective brain stimulation is unknown.

Rare but Serious

- None

Risks and side effects related to **long-term DBS therapy** are estimates based on scientific literature to date, and may include:

Likely

- None

Less Likely

- The brain electrodes or lead/extension connectors may move. Further surgery to re-adjust the location may be needed.
- Components or parts of the brain stimulation system may suffer mechanical breakage resulting in loss of therapy. Further surgery to replace the system parts may be needed.
- The brain stimulation system could stop because of an electrical or software malfunction, which could require further surgery if noninvasive attempts to restore the software did not succeed.
- Battery in the pulse generator could be prematurely depleted. This would require further surgery. Pulse generator battery service life depends on individual use, but for most device use, batteries should perform for more than 2 years.
- There may be an allergic reaction to the brain stimulation system. The system materials coming in contact with the tissues include titanium, polyurethane, silicone, and nylon. The body could also reject the system (as a foreign body).
- There is the possibility of tissue damage resulting from the programming settings or a malfunction of one of the parts of the brain stimulation system.
- Turning on the stimulator may produce side effects such as difficulty with speech, increased pain, abnormal sensations, dizziness, confusion, change in mood, thinking or emotions, or abnormal eye movements. It may have side effects that are unknown.

Rare but Serious

Thoughts of suicide: The possibility of suicidal thinking will be monitored throughout the study with questionnaires administered by the investigators. If you experience thoughts of suicide, tell the investigators and they will provide you with a mental health referral.

Reproductive risks: The reproductive risks of participating in this study are unknown. Women who are breastfeeding or potentially could become pregnant will not be allowed to participate in this study.

Radiation risks: This research study involves exposure to radiation. Not all this radiation exposure is necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately 6 mSv, which is equivalent to 2 times the yearly natural background of radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation may involve a low risk of cancer. If you are pregnant, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

Possible increased pain states may occur during Phase 2 in which placebo (i.e. no

stimulation) sessions are used. You will be closely monitored during the study and efforts will be made to decrease any periods of the study associated with possible increased pain states. If you decide to take a break from the study during Phase 3, there is a risk of increased pain states because you are stopping stimulation that may be providing you relief, allowing your pain to increase again.

Unknown Risks: Brain activity recording may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Risks and side effects related to **explant of the DBS electrodes and device** if you choose to do so are similar to implant of the device and include.

Likely

- Temporary pain at the surgery sites
- Temporary headache after surgery

Less Likely

- Seizures
- Infection in areas of the body in which the device comes into contact (i.e. brain, neck, chest) could lead to irritation or life-threatening illness which would require further surgery to remove all or parts of the device. Risks of removing the device may involve temporary pain at the surgery sites and temporary headache after surgery.
- Confusion or attention problems
- Muscle weakness around forehead that may interfere with keeping the eyes open and could lead to permanent weakness.

Rare but Serious

- Bleeding inside the brain (stroke), that could cause paralysis, coma, or death
- Harmful reaction to anesthetic agents
- Leaking of the fluid surrounding the brain
- Air embolism (air bubble that enters an exposed blood vessel on the surface of the brain or in the skull bone, which can travel to the heart and possibly lung, a potentially life-threatening condition).

For more information about risks and side effects, ask your study doctors.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study, although one of the

goals of the study is to provide pain relief. Pain treatment from using the Activa PC+S has not yet been shown, but DBS with similar systems have been shown to give pain relief for certain patients. This study will help doctors learn more about how DBS may affect brain activity related to pain, and it is hoped that this information will help in the treatment of future patients with chronic pain. After the study ends, you will also have a choice to have the device remain implanted (and also after consultation with your doctors) if you have experienced pain relief from the study.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting standard pain treatment without being in a study.

- Other pain treatment alternatives such as different classes of pain medications, spinal injections, spinal cord stimulation and / or drug pump medical devices.

Please talk to your doctors about your choices before deciding if you will take part in this study and other options for pain treatment that are available to you.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

If suicidal thinking is identified during routine study monitoring, you will be referred for urgent psychiatric evaluation, which may involve a loss of privacy.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- UCSF's Institutional Review Board Committees
- The Food and Drug Administration (FDA), involved in keeping research safe for people.
- Medtronic, Inc., the company that makes the Activa PC+S device.
- Members of the Data and Safety Monitoring Board for this study, led by Dr. Line Jacques, a neurosurgeon at our home institution, who does not have direct involvement in this study but who has expertise in implantable devices, pain management and neurosurgery.
- Federal (NIH, Department of Defense) representatives, involved in providing some of the funding that supports this study.

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

What are the costs of taking part in this study?

The costs of all visits, treatments, and tests described above will be billed to you or your insurance carrier, with the exception of all implant devices and related materials (leads, electrodes, streaming intercepts, software, etc.), which will be provided by Medtronic. Insurance companies and other carriers sometimes refuse to pay the costs of treatment when individuals are participating in research. If this happens in your case, you will be billed for the care your insurance will not cover. Financial counselors are available through the hospital accounting department to discuss what your insurance carrier will and will not cover. You do not have to continue with the study (i.e. Undergo physical examination, brain scans or the surgery portion and the other phases of the study) until you know and have indication of coverage from your insurance on the specifics of what will and what will not be covered.

Will I be paid for taking part in this study?

For postoperative study visits starting at day 10 after surgery (a total of up to 37 postoperative visits), you will be reimbursed at the IRS rate for mileage driven from your home to UCSF and back. If you do not have a handicap placard, we will provide parking stickers to pay for parking at the UCSF parking garage. For patients living more than 60 miles away, you will be reimbursed for 1-night hotel charge up to $200 on the night before your visit.

What happens if I am injured because I took part in this study?

It is important that you tell the research staff and / or your study doctor, Prasad Shirvalkar, MD PhD, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him or the research staff at 415-502-1653, Monday through Friday, 8AM to 6PM.

Once eligibility has been established and you are officially enrolled in the study (before undergoing hospitalization and / or surgery), you will be given a contact number where you can access a physician pager service after hours and on weekends, if you feel an injury has occurred after hours.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information

about this, you may call the office of the Committee on Human Research at 415- 476-1814.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to research staff related to the study or your study doctors about any questions, concerns, or complaints you have about this study. Contact the research study at chronicpain@ucsf.edu or at 415-502-1653.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____	_____	
Printed Name of Patient	Signature of Patient	Date

_____	_____	
Printed name of person obtaining consent	Signature of person obtaining consent	Date