VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	**Characterization of Central Pain Syndrome in Survivors of Head and Neck Cancer**
Version Date:	**07/10/20**
PI:	**Dianne Lou, M.D., Ph.D.**

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?
You are being asked to take part in this research study because you have completed treatment for head and neck cancer at least six weeks ago or have been asked to participate as a healthy control patient. We are interested in studying the long-term symptoms and functional problems experienced by head and neck cancer patients. Many head and neck cancer patients have pain after they have completed treatment. Cancer and its treatment may change how the brain manages pain. This can make treatment of post-treatment pain more challenging for health care provides. In order to better manage post-treatment pain, we need to better understand how the brain is responding to pain. The purpose of this study is to look at the brain's response to pain using magnetic resonance imaging (MRI). A portion of the study will be spent obtaining different MRI scans of your brain while at rest. Another part of the study will involve delivery of varying degrees of pressure stimuli to your thumbnail and you will then be asked to rate your pain while we obtain images of your brain. Finally, we will obtain a blood sample for further studies. We anticipate enrolling a total of 75 patients who will ultimately undergo the MRI scans and provide blood samples.

The pressure stimulus will be delivered using a device called the IPC-1000. The IPC-1000 is a small device that you will hold in your hand while we obtain MRI scans. The device will deliver pressure to your thumbnail for five seconds at a time. We will repeat this several times while taking images of your brain. You will also be asked to rate your pain. This device is an investigational device which means that it is only used in studies. Approval by the Food and Drug Administration (FDA) is not required for the use of this device in this study.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

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There are no expected side effects related to participation in this study. However, some patients develop distress or anxiety when talking about their personal problems or situations. If this occurs during completion of the questionnaires or during the interview, an appointment will be made for counseling with our social worker.

Prior to undergoing MRI scans, you will be screened using the MRI screening tool. This tool identifies any contraindications to MRI such as claustrophobia, metal implants, non-MRI compatible devices, etc. There are no known major risks with an MRI scan. But, it is possible that harmful effects could be found out in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off during the MRI scan. Transdermal patches slowly deliver medicines through the skin. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of these patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch. Tell the study doctor that you are using a patch and why you are using it (such as, for pain, smoking cessation, hormones). Ask your doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure. Tell the MRI facility that you are using a patch. You should do this when making your appointment and during the health history questions you are asked when you arrive for your appointment.

The MRI used in this study has been used in human research for several years and no risks have been identified. However some people may experience discomforts such as nausea, dizziness, flashing lights in the eyes, and a metal taste in the mouth. These discomforts are most likely to occur as a result of rapid head movement in or near the MRI machine. For this reason, you should try not to move, especially your head, while you are inside the MRI.

There are no known risks of having MRI scans without contrast while pregnant. However, there may be risks that are unknown. To be safe, pregnant patients will be excluded from the study. Those of child-bearing age will be asked to take a pregnancy test.

In addition, you will be positioned and padded as needed to prevent any discomfort during the scanning process. If you are unable to complete the scan at any time or desire termination of the scan, the study will be canceled.

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The risks associated with blood draws include infection, bleeding, pain, accidental arterial puncture, bruising, and the need for multiple attempts. Only trained study personnel will perform blood draws to reduce these complications.

The risks associated with the use of the IPC-1000 pressure stimulator, subjects may experience discomfort to the thumb during testing. This is a normal response. For most subjects, this discomfort will dissipate immediately following the removal of the pressure stimulus from the thumbnail. It can be expected that some subjects may experience mild thumb tenderness for 1-2 days

Risks that are not known:
Since this study does not include medications or an intervention, it is highly unlikely that there are any unknown risks to study participation. Nonetheless, unanticipated problems may occur when participating in any research activity.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: Your participation could provide insight into the pain and other symptoms that develop in some patients following head and neck cancer treatment. This, in turn, could help physicians learn how to better treat these problems.

There are no direct benefits to you from being in this study.

Procedures to be followed:
If you agree to participate, you will be asked to participate in two tests where you will rate your pain to several pressure stimuli. The first test consists of delivery of a pressure stimulus to your dominant thumbnail for 5 seconds after which you will rate your pain on a scale of 0-100. After a brief rest period, the stimulator will deliver a slightly higher pressure stimulus to your thumbnail for 5 seconds after which point you will be asked to rate you pain again. This process will repeat until you rate the pain more than 80/100, reach a pre-set maximum pressure, or if you ask us to stop.

After a 10 minute break, we will perform a second test. This test consists of delivery of a pressure stimulus to your non-dominant thumbnail for 5 seconds after which you will rate you pain on a scale of 0-100. After a rest period, the process will repeat again for a total of 8 additional times.

Next, you will complete a series of questionnaires that will be administered on the computer. Completion of the questionnaires will take approximately 30 minutes. Your scores will be reviewed by the study staff.

You will then be scheduled for an MRI scan. An MRI scan is does not use x-rays. Instead, they use a strong magnet and radio waves, like those used in an AM/FM radio to make pictures of your body. The

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MRI session will be divided into three parts. During the first part of the session, we will obtain an MRI scan where you will stay still for a period of 10-20 minutes. For the next scan, the pressure stimulator will deliver a pressure to your thumbnail at a set level for 5 seconds followed by a rest period. This will occur several times during the scan. At the end of the scan, you will be asked to rate your pain. Then we will repeat this process again one more time. We will obtain one last scan while at rest. Finally, a blood sample will be collected to analyze your DNA, RNA, and/or proteins before or after the MRI scans. The entire process will take about 60-90 minutes.

You may not be able to have this scan if you have a device in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, cochlear implants, and/or are pregnant. Also, you may not be able to have this scan if you have an iron-based tattoos, pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye). Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. Also, metal can sometimes cause poor pictures if it is close to the part of the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.

You will hear "hammering", clicking, or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them. During the scan, the MRI staff is able to hear and talk to you. You will also be able to hear the staff. They will be talking to you during your scan and may ask you to hold your breath, not move, or other simple tasks. You may be asked to lie very still throughout the scan.

In this study, the MRI scan is for research only. But, if we see something that is not normal, you will be told and asked to consult your doctor.

After conclusion of the MRI, we will draw blood for further studies. Upon completion of the questionnaires, blood draw and the MRI, your participation will end.

Payments for your time spent taking part in this study or expenses:
You will receive a $50 gift card upon completion of this study.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

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There are no plans for Vanderbilt [or the Sponsor] to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Dianne Lou at 615-936-1830 or my Faculty Advisor, Dr. Barbara Murphy at 615-936-8422. If you cannot reach the research staff, please page the study doctor at 615-835-9481.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
If you are unable to complete the questionnaires, undergo MRI scanning, or receive blood draws, the study staff may take you off of the study.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor.

Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. 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 Web site at any time

Confidentiality:
To protect your confidentiality, you will be assigned a participant identification number that will be attached to all of your information collected as a part of this study. Only the PI, Dr. Lou, her mentor, Dr. Murphy and designated study staff will have access to the list of participants and their identification number. After the data collection is completed, the list that links your name with the identification number will be destroyed. To minimize the potential for lost or misplaced data, you will fill out questionnaires on the computer.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Lou, and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

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Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you. Your samples may be subjected to partial or complete genome sequencing in the future.

Study Results:
The results of this study will not be shared with you unless you request it. A copy of the MRI scans and any processing of blood samples may be made available upon request upon the discretion of the research team. Please contact the study investigator for additional information.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

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Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date Signature of patient/volunteer

Consent obtained by:

Date Signature

Printed Name and Title Time

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Genetic Screening "Rider" for Consent Forms

Consent for Genetic Research

The purpose of this study is to look at genes (DNA and RNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample may be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.

A single blood sample of 10 milliliters will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

Blood samples – You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Dianne Lou, Dr. Barbara Murphy, and other authorized study personnel will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA or RNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

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At any time, you may ask to have your sample destroyed. You should contact Dr. Dianne Lou at 615-936-1830 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

Yes No

My blood/tissue sample may be stored/shared for future gene research.

Yes No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

Yes No

Signature: _____ Date: _____