Washington University in St. Louis

FOR IRB USE ONLY
IRB ID #: 201807162
APPROVAL DATE: 04/02/21
RELEASED DATE: 04/02/21
EXPIRATION DATE: 04/01/22

# INFORMED CONSENT DOCUMENT

**Project Title: A new method for identifying sensory changes in painful chemotherapy-induced peripheral neuropathy (CIPN): a feasibility study**

**Principal Investigator: Simon Haroutounian**

**Research Team Contact: Karen Frey – 314-454-5980**

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

## WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have received one of the following chemotherapies for your cancer, oxaliplatin, cisplatin, paclitaxel, docetaxel or any combination of these, and you may or may not have pain in your feet as a result of receiving this treatment.

The purpose of this research study is to test whether an investigational device [the Diode Laser fiber type Selective Stimulator (DLss)] can identify sensory changes that are unique to patients with painful chemotherapy induced peripheral neuropathy (CIPN) vs. patients who have received similar chemotherapy treatment but did not develop painful neuropathy. The confirmation of these sensory changes may lead to a new approach for early detection of CIPN. The Diode Laser fiber type Selective Stimulator (DLss) is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

## WHAT WILL HAPPEN DURING THIS STUDY?

We may have already talked with you by phone or in person and scheduled this visit specifically to discuss the study in detail with you so you can decide whether or not to participate.

If you decide to participate and give consent today, we will ask you questions about your pain conditions, your cancer diagnosis, other chronic illnesses or conditions that you have, and all the medications you take. We will also need to collect information from your medical record, such as the types of chemotherapy drugs you were given, the total amount of all doses you received, how long and how often you received chemotherapy, and the side effects that you have reported.

You will be given 3 questionnaires. The questionnaires ask you about your mood and quality of life. You may skip any questions that you would prefer not to answer.

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Next, sensory testing will be performed. Sensory testing consists of multiple tests on the surface of your feet to determine your skin sensitivity to laser stimulation, warm and cold temperatures, pricking and brushing. One of these sensory tests will include the use of the DLss device. These tests (except the laser stimulation) will also be performed on your upper arm. There are automatic shut-offs in the equipment used in this testing that will prevent any injury to you. You may also tell us to stop the testing at any time. The areas of skin to be tested with the DLss device will be shaved to avoid differences in light absorption and heating (if this has not been completed already).

A subset of participants may be asked to complete further sensory testing with a special imaging camera that will allow us to see redness (called cutaneous flare response) in the skin that cannot be seen with the naked eye. Five minutes after your sensory testing, we will stimulate the affected skin with the laser and then use a special imaging camera to take up to 6 pictures and video of the affected skin. We will only take images and video of the affected skin area to maintain your confidentiality.

During your testing, a representative from LasMed LLC., the manufacturer of laser stimulator equipment, may be present to observe the visit and provide technical support if needed.

**Will you save my samples or research data to use in future research studies?**

As part of this study, we are obtaining data in the form of questionnaires and sensory tests from you. We would like to use the information you provide for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding peripheral neuropathy, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your completed questionnaires you give up any property rights you may have in the questionnaires.

Your data will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

## HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 40 people will take part in this study conducted by investigators at Washington University. 20 people with painful CIPN and 20 people who did not develop painful CIPN after chemotherapy.

## HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 3-4 hours.

## WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

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*Likely / Common*

Mild

- Temporary pain

*Less Likely / Less Common*

Mild

- Risk of mild skin burn

*Rare*

Serious

- Risk of small but serious skin burn

**Potential risks from thermal testing**

Risk of injury from thermal pain testing is low. Thermal testing does produce low level pain, but the pain is temporary in nature and generally stops after the test and the pain you will experience is expected to be below your tolerance level. Additionally, you may stop any test at any time. With thermal stimulation there is a very slight risk of a burn, but this is risk has been lessened by keeping the heat at or below 125.6°F, which feels like the temperature of a hot tub and the testing device has built in a shut-down system to prevent the temperature from rising above 125.6°F.

**Potential risks from DLss**

There is a low risk of skin injury or burning by laser stimulation when used for pain testing, that occurs by overheating of skin surface. This laser irradiation penetrates the skin fairly deeply, and does not allow overheating of the skin's surface. We also use a short, concentrated pulse; this will activate nerve fiber but is not long enough in duration to cause tissue damage.

**Potential risks from imaging camera**

There are no known risks associated with use of the imaging camera.

**Women Capable of Becoming Pregnant**

You may not participate in this study if you are pregnant. If you are a woman capable of becoming pregnant, we will perform a pregnancy test before beginning this study.

**Questionnaires and Assessments**

Completing the questionnaires or assessments may cause emotional discomfort, boredom, or fatigue. You have the right, however, to refuse to answer any question for any reason.

**Breach of Confidentiality**

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

## WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because it may lead to a new approach for early detection of CIPN.

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**WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**
You will not have any costs for being in this research study.

**WILL I BE PAID FOR PARTICIPATING?**
You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will receive a $100 Target gift card and a parking pass for completing all the pre-study screening and study testing. If you only complete the pre-study screening you will receive a $25 Target gift card and a parking pass.

**WHO IS FUNDING THIS STUDY?**
The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

**WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?**
Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator, Simon Haroutounian, at 314-286-1715 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

**HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?**
Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- National Institutes of Health (NIH)
- LasMed, LLC
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems

to track billing information for research procedures.

- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

The research team will send study results to LasMed, LLC. Information sent to LasMed, LLC will be de-identified. LasMed, LLC will use this information to study the effectiveness of the device. In the future, LasMed, LLC may continue to use your health information that is collected as part of this study. For example, LasMed, LLC may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study device, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. LasMed, LLC may also share information from the study with regulatory agencies in foreign countries.

If you receive Medicare benefits, are injured as part of your participation in this research study and medical treatment relating to this injury is paid by anyone other than you or your insurance company, that payer will need to collect personal information about you. This information includes your name, date of birth, gender, social security number, Medicare identification number and information related to this research study. The payer will report this information to the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, during your participation in the study and for as long as the payer is required by CMS to report this information. If you do not want to release your personal or treatment related information you have the right to refuse reimbursement by the payer for any research injury. The payer will not use this information for any other purpose.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your protected health information relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your health care records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

To help protect your confidentiality, you will be assigned a study ID number and we will use that ID to manage all your study related information. This includes paper documents and electronic documents that we collect from you during your participation. Additionally, the key to the ID code linking code numbers to names will be kept at a separate location, under lock and key, and only the research team will have access to it. We will destroy the link between your ID and your identifiers at the end of the study. Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others. Sharing this information will allow others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

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

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the

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federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

**Are there additional protections for my health information?**

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

**If you decide not to sign this form, it will not affect**

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

**If you sign this form:**

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).

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- To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
        - The research team may only use and share information already collected for the study.
        - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
        - You will not be allowed to continue to participate in the study.

**IS BEING IN THIS STUDY VOLUNTARY?**

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

**What if I decide to withdraw from the study?**

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

**Will I receive new information about the study while participating?**

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

**Can someone else end my participation in this study?**

Under certain circumstances, the researchers or the study sponsor might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue, because your condition has become worse, because you are or became pregnant, because funding for the research study has ended.

**WHAT IF I HAVE QUESTIONS?**

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Karen Frey, 314-454-5980. If you experience a research-related injury, please contact: Karen Frey, 314-454-5980 or Dr. Simon Haroutounian at 314-286-1715.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the

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research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

**Do not sign this form if today's date is after EXPIRATION DATE: 04/01/22.**

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

**Statement of Person Who Obtained Consent**

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)