CEDARS-SINAI MEDICAL CENTER

CONSENT FORM FOR RESEARCH

Title: VOXX HUMAN PERFORMANCE TECHNOLOGY SOCKS FOR CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY: A DOUBLE BLIND, RANDOMIZED, CROSSOVER TRIAL

SPONSOR: VOXXLIFE

PRINCIPAL INVESTIGATOR: ARASH ASHER, MD

STUDY CONTACT PHONE NUMBER AT CSMC: (424) 315-2215
STUDY CONTACT PHONE NUMBER AT TORRANCE: 310-750-3300 EXT 73422

AFTER HOURS CONTACT (24 HOURS): 310-423-1218

This research study is sponsored by VoxxLife. VoxxLife only reimburses Cedars-Sinai Medical Center for the costs associated with running the study; VoxxLife is not providing additional compensation to Cedars Sinai Medical Center or the Principal Investigator for their participation in the study.

1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are doing this study to examine the impact of Voxx HPT socks compared with normal socks on chemotherapy-induced peripheral neuropathy. We want to know whether wearing Voxx HPT socks makes this condition better, the same, or worse.

Voxx human performance technology (HPT) is a specific pattern woven into the fabric of Voxx HPT socks. The socks are drug-free and electrical-free.

You are being asked to take part in this research study because you have chemotherapy-induced peripheral neuropathy and have been diagnosed with cancer.

The study will enroll up to 30 people in total.

This research study is designed to test the use of Voxx HPT socks. These socks have not been approved by the U.S. Food and Drug Administration (FDA).

2. WHAT WILL HAPPEN DURING THE STUDY?

This section provides a general overview of what will happen during your participation in this study. Information included below should be considered along with the flowchart of procedures attached as an Appendix.

The flowchart shows a timeline for research-related or standard of care procedures that are involved in your participation in this study. **Research-related procedures** are those performed solely for the research. They would not be performed if you did not take part in the study. **Standard of care (routine)** procedures would be performed both as part of this study and if you do not participate in this study.

A table describing common medical procedures done solely for the purposes of monitoring and assessing your condition during this study is attached as an Appendix to the end of this consent form. Standard of care procedures that will be repeated or done at greater frequency are listed in the flow chart Appendix.

Overview of study:
This is a randomized, double-blind research study.

- "**Randomized**" means that you will be assigned to a study group by chance, like flipping a coin. You will be randomized into one study group and will have an equal chance of being placed in one of the groups described above.
- **"Double-blind"** means neither you nor the researchers will know what group you are assigned to.

This study has 2 study groups:

- Group A will be asked to wear Voxx HPT socks for 2 weeks, and then will be asked to wear regular socks for 2 weeks.
- Group B will be asked to wear regular socks for 2 weeks, and then will be asked to wear Voxx HPT socks for 2 weeks.

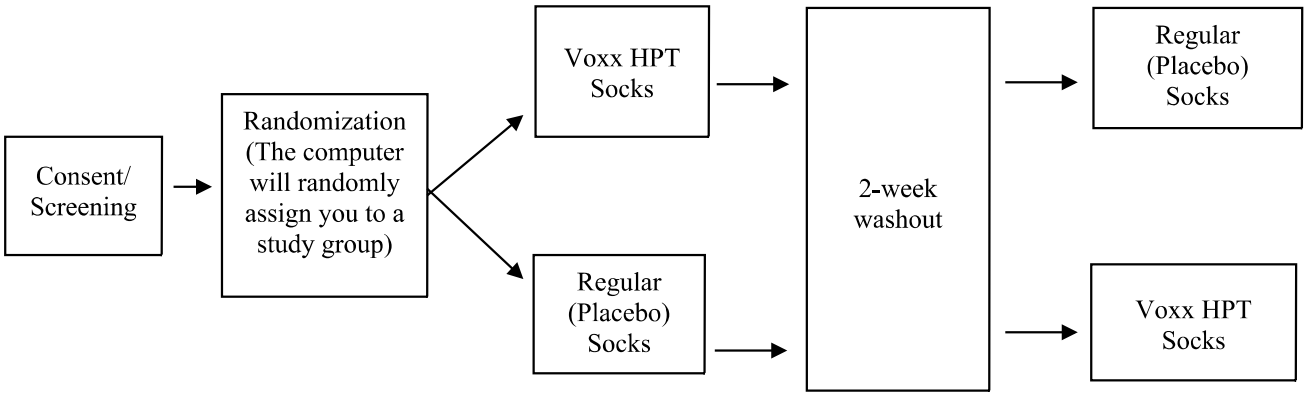
A computer will randomly assign you Group A or Group B. This is done because no one knows if the results experienced by the participants in one study group are better, the same, or worse than the results experienced by participants in the other. Once you are put in one group, you cannot switch to another group. Neither you nor your doctor can choose the group in which you will be placed.

Both study groups will use regular socks for 2 weeks and Voxx HPT socks for 2 weeks, but the order in which you wear the socks will randomized. Either of these different approaches could help your condition but could also cause side effects. This study will allow the researchers to learn whether the Voxx HPT socks are better, the same, or worse than the regular socks.

In order to properly follow the study's protocol (research plan), all participants will receive treatments and procedures that have been pre-determined by the protocol. In effect, the protocol describes which medications or procedures you will receive, rather than those decisions being made by your personal doctor or based on your preference. There may be options available outside of this study that you will not be able to receive while participating in this study. We do not believe you should be at any increased risk due to this limitation.

This is a placebo-controlled study. It will compare the effects (good or bad) of Voxx HPT socks against the effects of a placebo (normal sock) on the condition being studied in this research.

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How long will you be in the study?
We think you will be in this study for about 10 weeks. This time includes up to 4 weeks in screening with 1 study visit. This also includes 6 weeks on treatment with 3 study visits.

3. WHAT ARE THE POSSIBLE RISKS?

Risks of common medical procedures performed solely for research purposes are described in a table attached to the end of this consent form as an Appendix. Side effects and risks of standard of care procedures are not described in this consent form.

This section describes the possible risks and/or discomforts we anticipate you could experience that are related to the study procedures.

Risks of Voxx HPT Socks:

- Skin irritation of the foot or ankle
- Foot or ankle discomfort
- Temporary mild increase of pain in the foot

Participation in a double-blind study means that you may not be able to participate in other, similar trials since unblinding would generally only occur for emergent, life-threatening situations. We might not be able to tell you when you received the HPT socks or placebo socks in a situation where you would like to qualify for another research study. Because you may not know in which order you received the socks, in the future should you wish to participate in a different study that requires knowing what when you received the Voxx HPT socks, you may not be eligible to participate in the different study.

Follow-up Visit for Discontinuing Participants
While you are free to discontinue your participation at any time, we encourage you to complete a Final Study Visit. During this visit, we will conduct tests to collect safety data, and discuss any information that may be important to share with your treating physician.

4. ARE THERE BENEFITS IN TAKING PART IN THE STUDY?

If you agree to take part in this research study, there may or may not be direct medical benefit to you. The possible benefit of taking part in the research study is that your neuropathy symptoms may improve. However, no benefit is guaranteed. It is possible that your condition may remain unchanged or even get worse.

We hope the information learned from this research study will benefit other individuals with cancer in the future by helping us to learn whether Voxx HPT socks can help patients with chemotherapy-induced peripheral neuropathy.

5. WILL I BE INFORMED OF RESEARCH RESULTS?

Unanticipated Incidental Findings
If, unexpectedly, we find that results of your research procedures could suggest important medical information and we determine there is something you or your doctors can do in response to this finding, we will contact you using the last contact information provided by you. If necessary, we may recommend additional clinical testing to confirm the research finding. The cost of any additional testing and any related treatment will be your responsibility.

6. WHY WOULD MY PARTICIPATION BE STOPPED?

Your participation in this study may be stopped at any time by the researcher or the sponsor without your consent for any reason, including:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- If it is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- You do not follow the study procedures.

You may choose (or you may be required) to withdraw from certain parts of the study, but invited to continue with other parts. For example, you might stop using the socks, but continue with follow-up assessments or allow us to continue to collect data from your medical records. Separate written consent will be requested if your continued participation will involve procedures not described in this consent form.

7. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary, so you have the right to decline to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing not to participate will not affect the care you receive at Cedars-Sinai Health System.

If you decide not to take part in this study, you have other choices. For example:

- you may choose to be treated following the usual clinical approach such as steroids, topical medication, pain relievers, and/or physical therapy
- you may choose to take part in a different study at CSMC or elsewhere, if one is available
- you could decide not to be treated.

The researcher will discuss these options and their risks and benefits with you.

8. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC. 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 identifiable personal information will not be used. Organizations that may look at and/or copy your medical records for research oversight, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

Attached to this consent form is an "Authorization Form" that outlines with whom your information may be shared for the purposes of this research and under what circumstances.

We might share your information and/or research samples collected in this study with other researchers at Cedars-Sinai, other academic institutions, or third party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

A description of this clinical trial will be available on http://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 Website at any time.

9. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research related illness or injury?
A research-related injury or illness is a direct result of either the Study or Device or a procedure performed only as a part of this study and that is not part of your standard clinical medical treatment. Injury or illness related to your underlying medical condition or caused by non-research-related activities (such as treatment generally provided outside of the study) would not be considered research-related. If you are being treated for a research-related injury or illness, you will not pay for the costs of your appropriate medical or emergency room care. CSMC and the sponsor have no plans to pay for losses such as lost wages or pain and suffering. You do not waive any of your legal rights by signing this form.

10. FINANCIAL CONSIDERATIONS

Costs of Participation
You and your insurance company will not be charged for your participation in this research study. The Sponsor will cover the cost of all items, devices, and services required by this study, including any procedures required by the study.

Compensation for Participating
You will not be paid for taking part in this research study.

Financial Interest in the Research
The PI and institution have no potential financial conflict of interest with respect to this study.

11. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

Please contact the investigator listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP) Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

12. CONSENT PROVISIONS

If you sign this form below, it means that:

(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received and understand all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) You understand that by consenting to participate in the research you are not giving up any of your legal rights.
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study; and
(8) You have been provided with a copy of the "Experimental Subject's Bill of Rights", if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form and the Experimental Subject's Bill of Rights.

SIGNATURE PAGE

Consent Form for Research and
Authorization for Use and Disclosure of Identifiable Health Information (Research)

SIGNATURE BY THE PARTICIPANT

Main Research Study: *I hereby agree to participate in the research study described to me during the informed consent process and described in this informed consent form.* ***You will be given a signed copy of this form.***

Name of Participant (Print)	Signature	Date Signed

Authorization for Use and Disclosure of Identifiable Health Information (Research)): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with this "Authorization for Use and Disclosure of Identifiable Health Information (Research)" form attached as Appendix to this form.*

Name of Participant (Print)	Signature	Date Signed

SIGNATURE BY THE INVESTIGATOR: *I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.*

Name of Investigator (Print)	Signature	Date Signed

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APPENDIX: EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

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AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

- **USE AND DISCLOSURE OF HEALTH INFORMATION**

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Voxx Human Performance Technology Socks for Chemotherapy-Induced Peripheral Neuropathy: A Double Blind, Randomized, Controlled Crossover Trial" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☒ Laboratory tests
☒ Pathology reports
☒ Imaging reports (e.g., x-rays or scans)
☐ Photographs or videos of your image
☒ Doctor/clinic records
☒ Hospital/medical records
☒ Mental health records
☐ Billing records
☒ Other tests or other types of medical information: Questionnaires

- **WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?**

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, data analysis and use of research results in product development, and payment or reimbursement.

- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai is required by law to protect your private information. However, the recipients described above may re-disclose (or share) your information with other parties unless such sharing is prohibited by law.

- **WHEN WILL MY AUTHORIZATION EXPIRE?**

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

- **REVOKING AUTHORIZATION**

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

- **NOTICE OF RIGHTS AND OTHER INFORMATION**

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. The Research Team may not condition (withhold or refuse) treating you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

APPENDIX: FLOWCHART OF PROCEDURES

	Screening	**T0** (Baseline)		*Treatment*				**T1**		*Crossover Treatment*				**T2** (End of Treatment)
Day			**0**	**1**	**3**	**7**	**8-14**	**15**	**28**	**29**	**31**	**35**	**36-42**	**43**
Week				**1**	**1**	**1**	**2**	**3**	**4**	**5**	**5**	**5**	**6**	**7**
Informed Consent	X													
Medical History	X													
Concomitant Medications of Interest	X	X						X						X
Pain Assessment (Self-Report)	X													
Assessment of Eligibility	X													
Demographics Questionnaire		X												
Total Neuropathy Score clinical (TNSc)		X						X						X
Timed Up and Go Test		X						X						X
FACT/GOG-NTX – Neurotoxicity Subscale		X						X						X
PROMIS-29		X						X						X
ESAS		X						X						X
Socks Dispensed to Patients		X						X						
Socks Returned by Patients								X						X
Treatment Implementation				Continuous Sock Wearing				*Washout period*		Continuous Sock Wearing				
Sock Diary Entries				*Daily Entries*						*Daily Entries*				
Sock Diary Submission								X						X
Patient Reminder Phone Calls			X		X	X			X		X	X		
Adverse Event Monitoring					X	X					X	X		

APPENDIX: Detailed Description of Common Medical Procedures Performed for Research Purposes and Associated Risks

The procedures listed below are often performed as part of routine care for a person with your condition. They are being repeated or performed more frequently as part of this research. However, the risks associated with each procedure should be comparable to what you would experience even if you were undergoing the procedure outside this research study.

Study Procedure	Related Risks
Total Neuropathy Score clinical: A physician or nurse will assess your current neuropathy levels by asking you questions and testing your reflexes, your strength, and your ability to feel objects and vibrations.	You may feel discomfort or mild pain during this test.
Times Up and Go Test: You will be asked to stand up from a chair, walk 3 meters (about 10 feet), turn around, walk back, and sit down. The test is timed. You will be observed during the test by study personnel.	There is a rare possibility of fainting while you perform the test. All medical procedures will be done in the presence of a study staff member in order to minimize the occurrence of such untoward events.
Concomitant Medications of Interest: Staff will access your medical records to review what medications you take. You may also be asked about your previous and current medications.	There are no physical risks associated with this procedure.
Medical History Review: You will be asked about your medical and surgical history with attention to your neuropathy and medical treatment.	There are no physical risks associated with this procedure.
Questionnaires: You will be asked to complete a questionnaire. We will ask questions to evaluate your pain level, your neuropathy symptoms, your quality of life, and how much you have worn the socks. We think it should take about 15 minutes to complete the questionnaires. Questionnaires will ask you to respond to questions about coping mechanisms and instances of depression and anxiety, as well as current pain levels.	If you feel uncomfortable or embarrassed answering any question, you may skip it. The questionnaire will be labeled with a unique study number that will link your identity so that only the research team can recognize you.
Demographic Information: You will be asked about your age, gender, race, and ethnicity.	There are no physical risks associated with this procedure.