Study Title: Safety and Efficacy of the Noxsano Wound Care Bandage: A First-in-Human Study

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OHIOHEALTH RESEARCH INSTITUTE
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM
FOR HEALTHY VOLUNTEERS

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IRB Protocol Number: 1331496

Principal Investigator: Mitch Silver, DO

Study Funder: Noxsano, Inc.

Overview of Participation in Research

- We are conducting a clinical trial (a type of research study), which includes only participants who voluntarily choose to take part in the research study. You are being asked to take part in this study because you are a "healthy volunteer," who does not have any wounds on your legs, ankles, and/or feet.
- The purpose of the study is to determine the safety of the study device (the Noxsano Bandage) in healthy volunteers without wounds, and involves wearing a Noxsano Bandage on your lower left leg.
- If you choose to participate, your participation will involve approximately 7 visits over the course of 4.5 weeks.
- Because the results of the research are unknown, participation in research includes risks. If you choose to participate in the research, you may experience irritation of the skin or other side effects, which will be described in further detail below.
- You will not experience direct benefit from participating in this study. In the future the information from this study will help doctors learn more about the Noxsano Bandage as a treatment for non-healing wounds.
- Noxsano Inc. is funding this study and providing the bandages to OhioHealth free of charge.
- This research study is supported by Noxsano Inc. The Principal Covered Individual of this medical research study might benefit financially from this study. The Institutional Review Board has reviewed the possibility of financial benefit. They believe that the possible financial benefit to the Principal Covered Individual is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.
- You can choose not to participate in this study without penalty or loss of benefit.

1. What is involved if I participate in this study?

Reason for Conducting the Research: The purpose of this study is to determine the safety of the study device (the Noxsano Bandage) in healthy volunteers without wounds. The Noxsano Bandage is currently not in routine use for

patients at OhioHealth or other hospitals, and has not been tested for use in humans. Testing in animals has been done but it is unclear whether the animal data will predict what will happen when the Noxsano bandage is used on humans.

Description of the Research Procedures: If you take part in this study, you will have the following tests and procedures:

Assessment	**Screening** *(via phone)*	**Baseline**	**tion: Day 0Study Device**	**3 ± 0 days Treatment:**	**ry 7 ± 2 daysFollow-Up:**	**Unscheduled Visit**
Informed Consent		x				
Medical history	x					
Current medications	x	x	x	x	x	x
Critical Limb Care Center (Riverside Methodist Hospital Wound Center) visit (research-only)			x	x	x	
OhioHealth Research Institute Clinic visit (research-only)		x				
Shaving of left posterior calf		x				
Photograph			x	x	x	
Noxsano Bandage application			x			
Safety and Adverse Reactions (SAR) Questionnaire			x	x	x	

- **Screening (over the phone)**
  - We will call you and ask about your medical history and any over-the-counter medications you are taking to confirm your ability to participate in this study.
- **Baseline**
  - After you sign this consent form, the study staff will shave an area on your left calf (lower back leg) to apply the bandage at your next visit.
- **Study Device Application, Day 0 (within 1-3 days of the Baseline visit)**
  - A photograph will be taken of the shaved calf area prior to the study doctor putting the bandage on for you.
  - The study doctor will put the bandage on your leg, and then you will complete a questionnaire with a study staff member regarding any side effects.
- **Treatment, Day 3**
  - A photograph will be taken of your left calf area after the bandage is removed by the study doctor.

- You will complete a questionnaire regarding any side effects since your last visit.

- **Follow-Up Visits (every week for 4 weeks)**
  - A photograph will be taken of the area where the bandage was previously placed.
  - You will complete a questionnaire regarding any side effects since your last visit.
- **Unscheduled Visits**
  - If you call the study doctor due to any side effects or questions and are scheduled to come in to the Critical Limb Care Center, we will look at any notes from the doctor and any medications given.
  - You will complete a questionnaire regarding any side effects since your last visit.
  - A photograph will be taken of the area where the bandage was previously placed.

Participation in Research is Voluntary: You can stop being a part of this study at any time. If you do choose to stop participating, you may want to consult with the study doctor.

Options Instead of Participating in the Research: Instead of being in this study, you have the following options:

- You may choose not to participate in the study.

Before you make a decision about participating, please take the time to discuss your decision about participating with the researchers, your doctor, your friends or family, or others. If you have any questions about what is involved with the study, please ask the researchers so you can make an informed decision.

Number of People Participating in this Study: There are expected to be 20 participants enrolled into this study overall. There are expected to be 20 participants enrolled at OhioHealth Riverside Methodist Hospital.

2. *What bad things might happen if I participate in this research?*

Risks of Participating in the Research: There are always risks of participating in research. Some are minimal risk that could happen even if you do not participate, such as breach of confidentiality.

Other risks can be more serious. Risks and side effects related to the Noxsano Bandage include:

- Common:
  - Itchy or dry skin
  - Pain
- Uncommon, but serious:
  - Red skin
  - Swollen skin
  - Skin breakdown (rough or patchy skin)
  - Change in skin color
  - Increased blood flow (increased warmth of the skin)
- Rare:

- Fever
- Nausea or vomiting
- Low blood pressure
- Infection
- Allergic reaction

We expect side effects, if they happen, to start during the 3 days of bandage wear and clear up within 7-10 days of removal. However, some people may take longer due to the nature of their skin healing (some people heal faster than others), and could take up to 30 days. Because this is an early feasibility study, not all risks are known. In addition to the side effects listed above, there could be other unknown side effects.

Potential risks to unborn babies: Because the drugs in the study procedures can affect an unborn baby, you should not become pregnant while on this study. You should not nurse your baby while on this study. Ask about counseling and more information about preventing pregnancy.

Ending Participation in the Study: Your study doctor may decide to take you off this study if you do not return for follow-up visits. Participation is completely voluntary. However, if you decide to stop being in the study, please talk to the researchers first.

New Information Affecting Willingness to Continue Participation: You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.

Information Relevant to Future Treatment: If the researchers discover information that may have an impact on your non-research related medical treatment, this information will be shared with you at the time of discovery or your next follow-up with the study doctors .

Questions, Concerns, or Complaints Related to the Study: If you have questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Mitch Silver, DO at 614-566-1250 .

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Human Subjects Protections at 614-566-1748.

3. Are there any potential benefits I might experience by participating in the study?

Potential for Direct Benefit: If you agree to participate, you are not expected to experience direct benefit.

Potential Benefit to Others in the Future: Even if you do not receive any direct benefit, the researchers hope that the information from this study will help doctors learn more about the Noxsano Bandage as a treatment for non-healing wounds. This information could help future patients with this condition .

4. *Are there any costs that I will have to pay to participate in the study?*

Costs of Participating in the Research: The bandages will be provided to you free of charge. It is not expected that participation will cost anything more than your time.

Cost of Medical Procedures for Research: While you are in this study, you may have tests, procedures, and exams that are part of your routine medical care. The expense for routine medical care will not be paid for by the study and will be billed to your medical insurance.

If your medical insurance does not pay for this routine medical care, you will be billed for the cost of medical care related to your condition, including but not limited to tests, deductibles, co-payments, study doctor and clinic fees, hospitalization and procedures.

Payment for Harm Caused by the Research: In the case of physical, psychological, or other harm resulting from this study, emergency medical treatment will be provided as necessary. You or your insurance company will be financially responsible for this emergency medical treatment, continuing medical care and/or hospitalization. OhioHealth Corporation has no funds set aside to compensate you in the event of injury or illness.

5. *Will I be paid for taking part in this research study?*

OhioHealth employees volunteering to participate in this study will not be paid for taking part in this research.

If you are not an OhioHealth employee, you will receive $25 for the completion of the baseline visit, Day 3 visit (completion of treatment) and each completed follow-up visit (Days 10, 17, 24, and 31), for a potential total of $150. If you discontinue (stop) study participation due to unacceptable side effects, you will receive a one-time discontinuation payment of $25. Talk to your study coordinator about how you will be paid. By law, payments to subjects are considered taxable income.

6. *Will information or biological samples (e.g., blood, urine, etc.) be collected from me?*

Information Collected for the Research: We will collect personally identifiable information from you that will be used in the research and kept confidential, as described below.

Biological Samples Collected for the Research: We will not collect any biological samples from you for the purposes of the research.

Future Use of Information or Samples: In the future, your information collected for this study might be shared with other researchers. If we do this, you will not have an option to consent to the future research, whether or not to share your information with other researchers or use them for future research studies, even if all of the information that can identify you personally has been removed.

7. Who will be able to access information about me and will it be kept confidential?

What information may be used and given to others?

The study doctor or study staff will have access to your personal and medical information. For example:

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research study;
- Records about the study treatment you received;
- Information that may include your name, address, telephone number, social security number, date of birth or a number associated with you as an individual

Who might have access to this information?

- Your study-related information may be placed in your permanent medical record, clinic or doctors' office records.
- Authorized OhioHealth staff not directly involved in the study may be aware that you are participating in a research study and have access to your information.
- The Funder of this research study. "Funder" means any persons or companies that are:
    - Assisting with the drug or device manufacturing
    - Funding this research study
    - Noxsano, Inc.
    - Working for or with Noxsano, Inc.
    - Owned by Noxsano, Inc.

Your information <u>may</u> be given to parties, such as:

- The U.S. Food and Drug Administration (FDA),

- Department of Health and Human Services (DHHS) agencies,
- Representatives of governmental financial agencies,
- OhioHealth Corporate Ethics and Compliance
- OhioHealth Office of Research Compliance
- OhioHealth Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research study,
- to study the results, and
- to see if the research study was done properly.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to take part in this research study.

May I review or copy my information?

While the research study is in progress, your access to your study records will be temporarily suspended. You may review or copy your information after the study is complete.

May I withdraw or revoke (cancel) my permission?

You may withdraw or take away your permission to use and disclose your health information at any time. You may do this by sending a written request to the study doctor at:

- Mitch Silver, DO
- OhioHealth Riverside Methodist Hospital
  3525 Olentangy River Road
  Columbus, OH 43214

If you withdraw your authorization:

- Your participation in the study will end
- The study staff will stop collecting your medical information
- Information that has already been gathered may still be used and given to others.

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Is my health information protected after it has been given to others?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Once your information is disclosed to the study Funder, the IRB or the government agencies described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by federal privacy regulations.

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.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the OhioHealth Corporation Office of Ethics and Compliance at 614-544-4200.

Statement of Consent and HIPAA Research Authorization

I hereby freely and voluntarily consent to take part in the research study described above. This consent is given based on the verbal and written information provided and the understanding that I am medically and physically qualified to take part in this study. I am free to ask questions at any time.

I have the option to decline to take part or to withdraw from the study at any time without incurring any penalty or loss of benefits otherwise available, including medical care at this institution.

My signature below indicates that I voluntarily agree to take part in this study and that I authorize the use and disclosure of my information in connection with the study. I will receive a signed copy of this consent and authorization form.

Participant

_____	_____	_____
Printed Name of Participant	**Signature of Participant***	**Date / Time**

Investigator / Research Staff

_____	_____	_____
Printed Name of Person Obtaining Consent	**Signature of Person Obtaining Consent**	**Date / Time**
_____	_____	_____
Printed Name of Investigator	**Signature of Investigator**	**Date / Time**

Witness (if applicable)

_____	_____	_____
Printed Name of Witness	**Signature of Witness**	**Date / Time**