Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Study: A single center pilot study to examine the effect of NATROX® Oxygen Wound Therapy on non-healing wounds and the practical implication of introducing a remote monitoring and telehealth solution to manage these complex patients in the home care setting.

Principal Investigator: Aliza Lee DPM, MS **VAMC:** Salem

OVERVIEW AND KEY INFORMATION

- This research study is being conducted using a new battery-operated oxygen wound therapy system called NATROX® system.
- The study will look at two things: how well does it work in reducing wound size during the 12 week study, and how effective is it for remote wound monitoring.
- If you wish to participate in this study, your study doctor will first determine if you are eligible to participate. If you meet all of the criteria, you will be enrolled.
- You will need to have, at minimum, 2 face-to-face visits during the first 4 weeks of study and then every 4 weeks until the end of study. There will be weekly telehealth visits and additional face-to-face visits may be scheduled as determined by the treatment team.
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- Some risks of this study include inflammation of the tissue, including pain, potential enlargement of the ulcer, or infection as may occur with any wound . The risk of using an offloading device/boot includes instability while walking or standing and inability to judge foot pedal pressure while driving.
- Your participation in this study is completely voluntary. You may choose not to participate in this study. You should discuss your wound treatment options with your doctor.

Please read this form carefully. You are being asked to participate in this research study because you *have an ulcer (wound).* This study is voluntary and will include only people who choose to take part. Ask your study doctor or study staff to explain any words or information that you do not understand. It is important that you understand the information on this form.

PURPOSE: This research study is being conducted using a new oxygen wound therapy system called NATROX®. A small battery-operated device generates moist oxygen safely from the atmosphere and delivers it to the wound via a sterile, single use oxygen delivery system. The study will be conducted by the study doctor listed on this form and his/her study staff. This is a single center pilot study enrolling 6-12 subjects.
If you agree (consent) to enter the study and sign/date this Informed Consent, you will go through a screening period that may last up to 2 weeks to determine your eligibility for the study. If you meet all

of the criteria, you will be enrolled. You will then continue in the study for 12 weeks of study treatment unless your wound heals.

During the 12-week study treatment portion of the study, you will return to the office for a minimum of 2 face-to-face visits during the first 4 weeks of study and then every 4 weeks until the end of study. There will be a weekly clinical review using telehealth so that we can keep a very close eye on your wound and follow the progress of your healing. Additional face-to-face visits may be scheduled as determined by the treatment team. If your wound has not completely healed following these visits, you will continue to receive standard wound treatment in the wound clinic. If your wound heals prior to the 12 weeks of therapy are done you would have completed the study and will no longer need study visits.

PROCEDURES:

The first step in participating in this research study is signing and dating this Informed Consent form. It is very important that you read it carefully and ask any questions. Informed Consent is a "process." It begins when you start reading this consent form and it continues throughout the course of the study. If at any time, while you're participating in the study you have questions, please feel free to contact either the study doctor or any of the study staff. A copy of the signed and dated consent form will be given to you to keep.

If you agree to participate in the study, you will be asked questions about your general health and well-being. Your answers will be used to help the study doctor or study staff to decide whether or not you're a candidate to enter into the study. Please provide us with as much information as you can, remembering that there are no right or wrong answers.

Procedures performed on the day you sign and date the consent form (Screening Day, Visit 1, Week 0):

1. A complete medical history and physical examination which includes taking your vital signs (blood pressure, heart rate, breathing rate, and temperature).
2. A complete wound history along with assessments for moisture control, infection, b, and touch sensation.

3. Blood tests may be ordered to check for any major uncontrolled medical disorders such as: serious cardiovascular, renal, liver or pulmonary disease, lupus, sickle cell anemia, malignant disease etc.
4. Your study doctor may order circulation studies such as an ABI ( ) or TcPO2 will be performed
5. Your wound will be treated with the standard of care; this may include cleansing and debridement (the removal of unhealthy tissue from the wound).
6. The wound will be photographed and measured as part of your wound assessment documentation. These photographs may be used for educational or publication purposes. There will be no way for anyone viewing the photographs to identify you; however, these photographs may be used in journal articles or on websites or shown at lectures for the sole purpose of education.
7. Assessments for wound infection, a quality of life survey, pain, and adverse events will be performed.
8. If there is suspicion of bone infection, an X-ray will be performed.
9. You will be assessed for and given an off-loading boot, if indicated, to wear that will protect your wound site and dressing. This off-loading boot is designed to take pressure off of the wound site.
10. Should you meet criteria for enrollment at the end of the screening visit, you will be enrolled and commence with the wound oxygen therapy using the NATROX® system with an adhesive foam dressing as the secondary dressing.
11. You will be instructed in the use and care of the NATROX® wound therapy system.
12. You will be issued a specially configured iPhone with all applications preloaded by the sponsor (eKare patient app and NATROX® patient library) along with any relevant personalized instruction and supplies. This may include a video of the dressing regimen to support self-application.
13. You will take a short 5 question survey on the eKare patient app on your study iPhone.
14. All data entered into the iPhone goes to the sponsor and is not VA data, therefore it is not protected by the VA.

Note: An optional additional visit each week may be added for dressing changes as indicated by provider assessments.

Visit 2, Week 1: This will be a telehealth visit.

1. You will photograph your wound after removing the secondary foam for clinical review during the visit.
2. Your wound will be measured by digital photography.
3. Assessments for wound infection, moisture control, offloading compliance, and adverse events will be performed.
4. You will take a short 5 question survey on the eKare patient app on your study iPhone.
5. You will treat your wound as instructed by your provider.

Note: You may be requested to come into clinic based upon the judgement of the provider.

Visit 3, Week 2: This will be a face-to-face visit.

1. Your wound will be measured by digital photography after removing the secondary foam.
2. Assessments for wound infection, pain, moisture control, offloading compliance, and adverse events will be performed.
3. Your wound will be treated with the standard of care; this may include cleansing and debridement (the removal of unhealthy tissue from the wound).
4. The provider will apply the NATROX® device and a secondary foam bandage.
5. You will take a short 5 question survey on the eKare patient app on your study iPhone.

Visit 4, Week 3: This will be a telehealth visit.

1. You will photograph your wound after removing the secondary foam for clinical review during the visit.
2. Your wound will be measured by digital photography.
3. Assessments for wound infection, moisture control, offloading compliance, and adverse events will be performed.
4. You will take a short 5 question survey on the eKare patient app on your study iPhone.
5. You will treat your wound as instructed by your provider.

Note: You may be requested to come into clinic based upon the judgement of the provider.

Visit 5, Week 4: This will be a face-to-face visit.

1. Your wound will be measured by digital photography after removing the secondary foam.
2. Assessments for wound infection, pain, moisture control, offloading compliance, and adverse events will be performed.
3. Your wound will be treated with the standard of care; this may include cleansing and debridement (the removal of unhealthy tissue from the wound).
4. The provider will apply the NATROX® device and a secondary foam bandage.
5. You will take a short 5 question survey on the eKare patient app on your study iPhone

Visit 6, Week 5: This will be a telehealth visit.

1. You will photograph your wound after removing the secondary foam for clinical review during the visit.
2. Your wound will be measured by digital photography.
3. Assessments for wound infection, moisture control, offloading compliance, and adverse events will be performed.
4. You will take a short 5 question survey on the eKare patient app on your study iPhone.
5. You will treat your wound as instructed by your provider.

Note: You may be requested to come into clinic based upon the judgement of the provider.

Visit 7, Week 6: This will be a telehealth visit (if possible, or face -to-face if needed).

1. You will photograph your wound after removing the secondary foam for clinical review during the visit.
2. Your wound will be measured by digital photography.
3. Assessments for wound infection, moisture control, offloading compliance, and adverse events will be performed.
4. You will take a short 5 question survey on the eKare patient app on your study iPhone.
5. You will treat your wound as instructed by your provider.

Note: You may be requested to come into clinic based upon the judgement of the provider

Visit 8, Week 7: This will be a telehealth visit.

1. You will photograph your wound after removing the secondary foam for clinical review during the visit.
2. Your wound will be measured by digital photography.
3. Assessments for wound infection, moisture control, offloading compliance, and adverse events will be performed.
4. You will take a short 5 question survey on the eKare patient app on your study iPhone.
5. You will treat your wound as instructed by your provider.

Note: You may be requested to come into clinic based upon the judgement of the provider

Visit 9, Week 8: This will be a telehealth visit.

1. You will photograph your wound after removing the secondary foam for clinical review during the visit.
2. Your wound will be measured by digital photography.
3. Assessments for wound infection, pain, moisture control, offloading compliance, and adverse events will be performed.
4. You will take a short 5 question survey on the eKare patient app on your study iPhone.
5. You will treat your wound as instructed by your provider.

Note: You may be requested to come into clinic based upon the judgement of the provider.

Visit 10, Week 9: This will be a telehealth visit.

1. You will photograph your wound after removing the secondary foam for clinical review during the visit.
2. Your wound will be measured by digital photography.
3. Assessments for wound infection, moisture control, offloading compliance, and adverse events will be performed.
4. You will take a short 5 question survey on the eKare patient app on your study iPhone.
5. You will treat your wound as instructed by your provider.

Note: You may be requested to come into clinic based upon the judgement of the provider.

Visit 11, Week 10: This will be a telehealth visit (if possible, or face -to-face if needed).

1. You will photograph your wound after removing the secondary foam for clinical review during the visit.
2. Your wound will be measured by digital photography.
3. Assessments for wound infection, moisture control, offloading compliance, and adverse events will be performed.
4. You will take a short 5 question survey on the eKare patient app on your study iPhone.
5. You will treat your wound as instructed by your provider.

Note: You may be requested to come into clinic based upon the judgement of the provider.

Visit 12, Week 11: This will be a telehealth visit.

1. You will photograph your wound after removing the secondary foam for clinical review during the visit.
2. Your wound will be measured by digital photography.
3. Assessments for wound infection, moisture control, offloading compliance, and adverse events will be performed.
4. You will take a short 5 question survey on the eKare patient app on your study iPhone.
5. You will treat your wound as instructed by your provider.

Note: You may be requested to come into clinic based upon the judgement of the provider.

Visit 13, Week 12: This will be a face-to-face visit end of study (exit) visit.

1. Your wound will be measured by digital photography after removing the secondary foam.
2. Assessments for wound infection, pain, moisture control, offloading compliance, quality of life survey, and adverse events will be performed.
3. Your wound will be treated with the standard of care; this may include cleansing and debridement (the removal of unhealthy tissue from the wound).
4. The provider will apply the NATROX® device and a secondary foam bandage.
5. You will take a short 5 question survey on the eKare patient app on your study iPhone.
6. You will need to return the iPhone issued to you for return to the sponsor.

Unscheduled Visit: This could be either a telehealth or face-to-face visit based upon provider judgement.

RISKS: Some risks of this study include inflammation of the tissue, including pain, potential enlargement of the ulcer, or infection as may occur with any wound. The risk of using an offloading device/boot includes instability while walking or standing and inability to judge foot pedal pressure while driving.

Because this device concentrates oxygen from the air, even though the amount is small and diffused under a bandage, care should be taken that there is no smoking or open flames near you when treatment is taking place.

Should there be any unwanted side effects, the investigator will closely monitor you.

Less likely risks of study:

- Questionnaires: Some people become uncomfortable at being asked questions about their pain and daily life; if, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

BENEFITS: There will be no direct benefit to you from participating in this study. We hope that the study treatment you receive will help your wound to heal during the study. However, this cannot be guaranteed. If your wound does not heal during the study, you will continue to receive standard therapy as before. The information that we get from this study may help us, and your doctor, to treat future patients with ulcers/wounds in a better way.

ALTERNATIVES: Your participation in this study is completely voluntary. You may choose not to participate in this study. Your decision not to participate will not affect your current or future access to medical care or any benefits to which you are entitled. You should discuss your wound treatment options with your doctor. These options include the use of commercially available medicines.

CONFIDENTIALITY: Your privacy is very important to us and the researchers will make every effort to protect it. Your private records will be maintained in locked cabinets in a locked office, data entered into the computer will be password-protected.

Subject Name: _____ **Date** _____

Title of Study: A single center pilot study to examine the effect of NATROX® Oxygen Wound Therapy on non-healing wounds and the practical implication of introducing a remote monitoring and telehealth solution to manage these complex patients in the home care setting.

Principal Investigator: Aliza Lee DPM, MS **VAMC:** Salem

The Salem VA Research & Development Committee and its subcommittees (i.e. the Institutional Review Board {IRB} and Safety Committee {SRS} which are committees that oversee research and protect the safety of research subjects) will have access to the records.
Federal agencies including, but not limited to the Office for Human Research Protection (OHRP), the Office of Research Oversight (ORO), Office of Research & Development (ORD), Office of General Counsel (OGC), Government Accountability Office (GAO), and the VA Office of the Inspector General (OIG) may have access to the records. The US Food and Drug Administration (FDA) also has access to the records and may choose to inspect research records that include the subject's individual medical records.

Only authorized representatives of the Sponsor, its designees, monitors, auditors, Institutional Review Boards/Ethics Committees, and applicable regulatory authorities will have access to your hospital records and data collected. This is necessary to ensure that the study is performed according to the approved protocol, and that data are correctly recorded. In addition, your general practitioner may be contacted if you agree to be in this study and your medical records may be obtained. All personnel involved in the study are required to maintain the confidentiality of your medical records and the data at all times in accordance with applicable laws and regulations.

There are organizations that may inspect your records. These include:

- The study Sponsor, NATROX® (Inotec AMD LTD), and its affiliates.
- Sponsor Monitor: Performed in house by NATROX® (Inotec AMD LTD).

Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you.
The Salem VA Research & Development Committee and its subcommittees (i.e. the Institutional Review Board {IRB} and Safety Committee {SRS} which are committees that oversee research and protect the safety of research subjects) will have access to the records.

RESEARCH-RELATED INJURIES:

- VA medical facilities, including joint VA-DoD federal health care centers, must provide necessary medical treatment (i.e., not just emergency treatment) to a research subject injured as a result of participation in a research study approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. This requirement does not apply to (1) treatment for injuries that result from non-compliance by a research subject

with study procedures or (2) research conducted for VA under a contract with an individual or a non-VA institution.

- Care for VA research subjects with research-related injuries must be provided in VA medical facilities, except in the following situations: (1) If VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility Directors shall contract for the needed care; (2) If inpatient care must be provided to a non-Veteran research subject with a research-related injury, VA medical facility Directors may contract for such care; or (3) If a research subject needs treatment in a medical emergency for a research-related injury, VA medical facility Directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.

- Subjects cannot be charged, nor their insurance billed, for research-related injuries.

- In case there are any medical problems or if you have questions, concerns, and/or complaints about the research study, you can call Dr. Lee at (540) 982-2463 ext. 4441 or a member of the study staff at ext. 2090 during the day. If calling after hours, the doctor on call for Podiatry can be reached by calling the operator at (540) 982-2463 ext. 0.

VOLUNTARY PARTICIPATION STATEMENT:

- Participation in the research is voluntary
- Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
- The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

COLLECTION OF IDENTIFIABLE PRIVATE INFORMATION or IDENTIFIABLE SPECIMENS:

- Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

UNFORESEEABLE RISKS: There may be risks which are currently unforeseeable.

Subject Name: _____ **Date** _____

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Principal Investigator: Aliza Lee DPM, MS **VAMC:** Salem

TERMINATION OF SUBJECT'S PARTICIPATION: You should call the investigator in charge of this study if you decide to stop taking part in the research study. The data collected on you to this point remains part of the study database and may not be removed.

- Subjects have the right to withdraw from the study at any time for any reason. The investigator also has the right to withdraw a subject from the study, if he/she deems it to be in the subject's best interest. It is recognized that an excessive rate of withdrawals may render the study uninterpretable and, therefore, it is desirable to avoid unnecessary withdrawals.
- While lack of venous access is not anticipated as a major problem, a subject will be withdrawn from the trial if the investigator cannot find venous access during the treatment study visits.
- If a subject misses more than 2 consecutive weekly visits during the treatment phase, the subject will be withdrawn from the study.

RESEARCH SUBJECT COSTS: You will not be charged for any of the study treatments or procedures. All clinic, professional, diagnostic, and laboratory fees for tests and procedures that are part of this study will be provided at no cost to you. You or your usual health care payer will be responsible for any other health care costs.

FINANCIAL COMPENSATION: You are eligible to receive $40 for each completed face-to-face visit and $20 for each virtually completed visit. The amount you will receive for the study visits may vary slightly depending upon the mix of face-to-face and virtual visits. The maximum you can be given for your participation in this study is $480. Payments that you receive for participating in a research study are considered taxable income per IRS regulations. "If you receive $600 or more per calendar year as a result of your participation in one or more research studies, your name, address, social security number, and amount of payment will be submitted to the Internal Revenue Service for tax reporting purposes."

You will be issued a ClinCard (Greenphire) through Salem Research Institute. Your name, address, social security number, e-mail, and telephone number will be requested. This is a specially designed debit card for clinical research onto which your funds will be loaded as appropriate. When a visit is completed, funds will be approved and loaded onto your card. The funds often times will be available immediately after being loaded and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, please call (866) 952-3795 or ask your study coordinator for a replacement ClinCard.

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging

rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out.
Any demographic information collected is stored in a secure fashion and will be kept completely confidential.

SIGNIFICANT NEW FINDINGS: If there are significant new findings during the course of the study, you will be notified in a timely manner by the researchers both verbally and in writing of any new information, findings or changes in the way the research will be done that might influence your willing to continue to take part in this study.

RESEARCH SUBJECT'S RIGHTS:

- You have read, or have had read to you all of the above information. Dr. Aliza Lee explained the study to you and has answered all your questions. The risks or discomforts and possible benefits and the alternatives of the study have been explained to you.

- The results of this study may be published but your identity and records will not be revealed unless required by law.

- In case there are any medical problems or if you have questions, concerns, and/or complaints about the research study, you can call Dr. Aliza Lee, or a member of the study staff, at 540-982-2463, ext.4441 during the day and the doctor on call for Podiatry at (540) 982-2463 ext. 0 after hours.
- In the event of illness or injury that you believe to be related to the study, or if you have any questions about your rights as a research subject, complaints or concerns, you can contact the Chairperson of the Institutional Review Board (IRB) or designee at 540-982-2463, ext.1568 or the Research and Development Office at 540-982-2463, ext. 2029.

- If you wish to contact someone other than the research study staff, you may call the Research & Development office at 540-982-2463, ext. 2029 or contact the Research Compliance Officer at 540-982-2463, ext. 1226.

Subject Name: _____ **Date** _____

Title of Study: A single center pilot study to examine the effect of NATROX® Oxygen Wound Therapy on non-healing wounds and the practical implication of introducing a remote monitoring and telehealth solution to manage these complex patients in the home care setting.

Principal Investigator: Aliza Lee DPM, MS **VAMC:** Salem

- If you wish to verify that this is an approved Salem VAMC research study or you are unable to reach the research study team during normal business hours, you may call the Research & Development office at 540-982-2463, ext. 2029.

- For applicable clinical trials, "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."

- No guarantees or assurances have been given to you since the results and the risks of an investigation are not always known beforehand. However, every reasonable precaution will be taken to protect your well-being. You have not released this institution from liability for negligence.

STATEMENT OF CONSENT: I have read this informed consent document and have been given the opportunity to ask questions. I understand that I will receive a signed copy of this informed consent document and the original signed document will be placed in my case history in the investigator files. I authorize the use of my identifiable information as described in this form.

I voluntarily consent to participate in this study. This research study and my rights as a research participant have been explained to me.

_____ _____

Signature of Subject Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of Person Obtaining Consent Date