# CONSENT FORM & INFORMATION SHEET

**Title of Research Study**: The Effects of the PillowsPlus Nasal Cannula (PPNC) on Oxygen During Sleep.

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**Background:** The study tests if the PillowPlus Nasal Cannula (PPNC) improves oxygen levels during sleep. The PPNC tries to improve oxygen delivery from portable oxygen devices and help people breathe better while sleeping.

**Purpose:** The study compares the PPNC to a regular nasal cannula and oxygen concentrator to see which one gives more oxygen during sleep. Participants are people needing long-term home oxygen.
We will compare oxygen levels and heart rates. We will use combinations of nasal devices and oxygen supplies. A pulse oximeter will take oxygen level and heart rate.
The research will help Pulmvita Inc. know how well the device works. We will gather opinions to improve comfort and fit. Right now the PPNC is not a licensed medical device by Health Canada. This study will be used for Health Canada approval. Health Canada approves the device for testing.

**Procedures:** If you want to be in the study, give your consent by signing your name on this form. Participation takes 3 nights. You will get instructions from the researcher. We will give you written instructions, a pulse oximeter, a portable oxygen concentrator, a standard oxygen concentrator, a standard cannula, and the PPNC.

The study has three parts:

1. Night one, participants get ready for bed. They attach the standard nasal cannula to the oxygen concentrator. They put on the cannula. Participants attach the pulse oximeter to the middle finger on their left hand. Participants set the oxygen to their usual, doctor-prescribed flow rate. They log flow rate on the Oxygen Flow Rate Log. Participants will go to sleep. When participants wake up they take off the pulse oximeter. For the rest of the day they use their usual oxygen delivery system.

2. Night two, participants attach the PPNC to the portable oxygen concentrator. They put on the PPNC. Participants attach the pulse oximeter to the middle finger on their left hand. Participants set the oxygen to their usual, doctor-prescribed flow rate. They log the flow rate using the Oxygen Flow Rate Log. Participants go to sleep. When participants wake up they take off the pulse oximeter. For the rest of the day they use their usual oxygen delivery system.

3. Night three, participants get ready for bed. They wear a standard cannula connected to a portable oxygen concentrator. Participants attach the pulse oximeter to the middle finger on their left hand. Participants set the oxygen to their usual, doctor-prescribed flow rate. They log the flow rate using the Oxygen Flow Rate Log. Participants go to sleep. When participants wake up they take off the pulse oximeter. For the rest of the day they use their usual oxygen delivery system.

Each morning, participants rate how comfortable the cannula was. After night three, participants return the equipment, questionnaires, and oxygen log to the pickup location.

A Study ID connects your data. The ID will make your results anonymous. Your name doesn't connect with your Study ID. Your data will only be linked with your Study ID.

If you have questions about the study you can talk with the PI. If you have questions later, you can contact the PI. Phone number and email are on this form.

**Compensation:** For taking part you receive $150 CAD each night, $450 maximum. Parking costs at the Centre for Advanced Medical Simulation will be paid. If you take part in the walk test you can receive an additional $150 CAD.

**Possible Benefits:** The study may help your community. If the device works well, it could help people who need supplemental oxygen.

**Possible Risks:** The monitoring equipment, or the activity (sleeping), may dry or irritate participants' nose. Participants will be at home using their usual oxygen flow rates. Consider these warnings from the PPNC and oxygen supply makers: 1) The PillowsPlus Nasal Cannula needs moderate patient participation. So, you must understand and follow the instructions. If you take strong sedatives or other mind-altering meds, do not use the system without a doctor's supervision. 2) If the PillowsPlus Nasal Cannula malfunctions, you may not receive the appropriate therapy. A readily available alternate or backup means of delivering your therapy,

such as a standard nasal oxygen cannula, should always be available. 3) The PillowsPlus Nasal Cannula is designed for use with oxygen sources that comply with local regulations for medical oxygen. 4) Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame. 5) The PillowsPlus Nasal Cannula could pose a risk of strangulation. To avoid strangulation, keep tubing away from children, pets, and closely supervise impaired persons. Do not route tubing around neck. 6) Please note it is unsafe to modify the PillowsPlus Nasal Cannula in any way not described in the instructions for use. 7) The PillowsPlus Nasal Cannula is intended for single-patient use. Do not share or reuse. 8) The PillowsPlus Nasal Cannula is only compatible with oxygen sources that use standard oxygen barbs for tubing connections. 9) No lubricants other than those recommended by the manufacturer are to be used. 10) This is an investigational device to be used by qualified investigators only.

**Confidentiality**: Your data will be confidential. We won't share data with the study funder (Alberta Innovates). We will collect names and dates of birth. Your name will not be connected to your data. . We will not use your name in any study results. We collect names to match them to Study IDs. This is for data removal or to contact people for future studies. Each participant will get a study ID number. A master list of names and study ID numbers will be kept in a locked file cabinet in a locked office on the NAIT campus. Only the PI can see the master list. We collect and examine all additional data anonymously. The Study ID will help tell participants apart. After data collection, if participants want their data taken out of the study, data can be taken out up to when the article is sent to a scholarly journal.

The results will be used to write an article for a journal and/or a conference presentation. The article or presentation will be based on all data and will highlight the general findings. Individual data will not be in the article. The study results will be shared with Health Canada for a medical device license application.

All data collected (e.g., SPO2) from the pulse oximeter will be stored on a secure, password-protected NAIT server. Only the PI can see it. The participant question forms will be kept in a locked file cabinet in a locked office. Only the PI can access it. All data will be kept for at least 5 years after the project ends. Then, we will delete the files from the server and destroy any paper records.

**Voluntary Participation:** You do not have to take part in this study. You can stop at any time and still be paid. Stopping won't affect your medical care. If you stop at any point during data collection your data will not be recorded. After you finish the study, you can remove your data by contacting the PI and giving your name or Study ID number. You don't have to answer any questions or take part in any stage of the study. By consenting to take part, you have not waived any rights to legal options in the event of research-related harm. You can say you want to stop taking part in the study to any member of the research team at any time.

Participants who want a report of the research findings can contact the PI using the email on this consent form.

**Perceived Conflict of Interest:** Some of the researchers on this consent form (D.V., C.C., A.M.) own Pulmvita Inc., which made the PPNC. Those researchers will not collect any data. Data collected in this study will be from instruments (the pulse oximeter) or by a researcher with no

part in Pulmvita Inc. and nothing to gain from this study. NAIT CAMS is not involved in any design or business decisions and receives no benefit from the sale of this product, financial or otherwise.

*Study Sponsor* Pulmvita Inc. is the study sponsor
*Study Funder* This study is funded by an Alberta Innovates Health Innovation Platform Partnership Grant # 202102243. This study is also funded by an Alberta Innovates Accelerating Innovations into CarE (AICE) – Validate Grant # 232402806.

Contact Information: If you have any questions, please contact:
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**Ethics Approval**: This research has been reviewed and approved by the University of Alberta and NAIT Research Ethics Board. If you have any questions regarding your rights as a research participant, you may contact the University of Alberta Research Ethics Office at reoffice@ualberta.ca. This office has no relationship with the researchers. You can also contact Lisa Slywka, Chair of the NAIT Research Ethics Board at reb@nait.ca or 780-471-8673. This office has no relationship with the researchers.

**Future Research:** The research team may do future research on the PPNC and may want to contact participants from this study for potential participation. If you want to be contacted, the researcher will ask for your email address at the end of the study. You may or may not agree to provide it. You will only be identified through your Study ID and contacted through the email you provide. If you want to be contacted please check the box below.

☐ I consent to be contacted about future research on the PillowPlus Nasal Cannula technology.

**Consent Statement**: I have read this form, and the research study has been explained to me. I have been allowed to ask questions, and my questions have been answered. If I have other questions, I know who to contact. I agree to participate in the research study described above and can receive a copy of this consent form. By signing below, I consent to participate in the study.

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|---|---|
| _____ | _____ |
| Participant Name | Participant Signature |
| _____ | |
| Date | |
| _____ | _____ |
| Witness Name | Witness Signature |
| _____ | |
| Date | |