

<b>Official Title:</b>	Impact of ambulatory oxygen delivery method on real-world activity and quality-of-life in patients with interstitial lung disease (ILD) or chronic obstructive pulmonary disease
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**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical Research Institute on Addictions

1021 Main Street | Buffalo, NY 14203

UB Federalwide Assurance ID#: FWA00008824

***Adult Consent to Participate in a Research Study***

***Title of research study: Impact of ambulatory oxygen delivery method on real-world activity and quality-of-life in patients with interstitial lung disease (ILD) or chronic obstructive pulmonary disease (COPD)***

***Version Date: 04/27/26***

***Investigator: Kristopher Clark, MD***

**Key Information:** The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

***Why am I being invited to take part in a research study?***

You are being invited to take part in a research study because you have been diagnosed with either a fibrotic form of interstitial lung disease (fILD) or chronic obstructive pulmonary disease (COPD). You may therefore have low oxygen levels in your blood when you are walking or being active.

***What should I know about a research study?***

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

***Why is this research being done?***

ILD and COPD are diseases which often affect how well oxygen can get from the lungs into the blood. Low blood oxygen levels may cause shortness of breath and can affect how patients feel and how they experience life. Many people with ILD and COPD only have low oxygen levels when they are walking or exercising. Low oxygen levels can be treated with prescribed oxygen. Oxygen that is only used with walking or exercise is called ambulatory oxygen. Ambulatory oxygen has been shown to improve exercise and symptoms when tested in a laboratory or clinic. It is not known whether ambulatory oxygen improves activity, symptoms, or quality-of-life when it is used during real-world activities at home or outside of the home. We also do not know if the tests we do in a clinic predict how much oxygen someone needs in the real world. There are different types of equipment that can give ambulatory oxygen. The type of equipment a patient receives may affect their symptoms or activity.

The purpose of this study is to collect data on how different ways of giving ambulatory oxygen affect activity, symptoms, and quality-of-life of patients with ILD or COPD. We will also check whether a commonly used hallway walk test can predict the amount of oxygen patients may need in the real-world. Understanding these issues may change how we care for patients with ILD or COPD who may need oxygen with activity.

### ***How long will the research last and what will I need to do?***

We expect that you will be in this research study for 6 to 8 weeks. You will need to complete several hallway walk tests as part of this study. These tests are used to measure your oxygen levels to find how much oxygen you need when walking. You will be asked to use different oxygen during your normal activities inside and outside of your home over 2 week periods. You will also be asked to do these activities without oxygen for 2 weeks. You will be given medical devices to collect information on your oxygen levels, activity, heart rate, and breathing rate during your activities. You will be asked to use the oxygen equipment at the settings the research given you, and to wear the medical devices whenever you are awake during the study period. You will be asked to fill out surveys on your symptoms and quality-of-life. Every 2 weeks you will return to the office so researchers can gather data from your equipment and devices and provide you with the equipment you will use for the next 2 weeks.

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

### ***Is there any way being in this study could be bad for me?***

You may have low oxygen levels during your activity. This will most likely happen during time when you are not using oxygen equipment. Low oxygen levels may make you feel short of breath or cause other symptoms. These symptoms will likely go away after you rest for a few minutes. We have no evidence to suggest that brief episodes of low oxygen levels occurring over the length of this study will cause you any short-term or long-term harm.

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

### ***Will being in this study help me in any way?***

We cannot promise being in this study will help you in any way. You may have improvement in your breathing symptoms or activity while using oxygen equipment. If so, you can discuss this with your treating providers after the study to see if you should continue to use oxygen.

### ***What happens if I do not want to be in this research?***

Participation in research is completely voluntary. You may choose not to enroll in this study. Instead of being in this research study, your alternative is to not participate.

**Detailed Information:** The following is more detailed information about this study in addition to the information listed above.

### ***Who can I talk to?***

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team (Kristopher Clark, MD, Primary Investigator, 716-961-9900, [kclark4@buffalo.edu](mailto:kclark4@buffalo.edu)). You may also contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

This research has been reviewed and approved by an Institutional Review Board (“IRB”). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

### ***How many people will be studied?***

We expect about 24 people will be in this research study.

### ***What happens if I say yes, I want to be in this research?***

#### **Screening Procedures:**

- If you agree to participate in this study, you will first complete a screening questionnaire and walk test to determine if you are eligible for the study. You will also give researchers permission to contact your treating providers to obtain information on your medical history which will also be used to confirm your eligibility for the study. The screening process should last no more than 1 hour.

#### **Study Procedures:**

- Once you are determined to be eligible, you will complete a series of additional walk tests using a portable oxygen concentrator and a portable oxygen tank. These tests will determine how much oxygen you need from these devices. We will also measure your height, weight, and other vital signs, and ask you to complete several surveys about your symptoms and quality-of-life.
- If possible, these initial tests and surveys will be done on the same day as your screening tests. However, if the researchers need to review your medical information further, then you may be asked to return within 14 days of the screening visit to complete these. Completion of these tests and survey should take no more than 3 hours.
- You will spend 2-weeks periods with the portable concentrator, portable tanks, or no oxygen for a total of 6-weeks to complete the entire study. The order you will be assigned will be chosen by chance, like flipping a coin.

- For the weeks when you are asked to use the oxygen equipment, you will need to use the equipment whenever you are active inside or outside of your home. You will be told what settings to use for the oxygen equipment. You will be asked to not adjust these settings during the study.
- You will be given medical devices to wear whenever you are active inside or outside of your home during the study. This includes an ear clip called Oxiwear to measure your oxygen levels and a wristwatch-like device called ActiGraph LEAP to measure your activity, heart rate, heart rhythm, and breathing rate. A small number of participants will be given a device called Nonin WristOx2 to wear on their finger for 2 days each 2-week period for more oxygen level measurements. You will be taught how to use and charge these devices.
- You will return to the office every 2 weeks. During these visits, you will repeat the walk test, have your vital signs re-measured, and fill out updated surveys. Researchers will download data from your equipment and devices. You will be given new equipment to use for the next 2-week period. These return visits should last no more than 2 hours.

To be eligible for this study, you must have:

- either ILD or COPD
- a normal oxygen level when breathing room air at rest
- a low oxygen level when breathing room air
- an adequate oxygen level while walking with the oxygen equipment used in this study
- a smartphone that will be compatible with the Oxiwear device and the ability to connect to the internet to upload Oxiwear data

If you are found to not be eligible for the study, you will be referred back to your treating provider for further testing and treatment.

During the entire time you are in this study, you will be asked to not check your oxygen levels yourself. You will also be asked to not change any of the oxygen equipment settings.

By participating in this study and signing this consent, you are giving researchers permission to provide your name, phone number, and address to Health Systems Services. This information is needed for them to provide you with the oxygen tanks used in this study. They will deliver these tanks to your home and refill the tanks when needed during the 2-weeks when you are assigned to use oxygen tanks. They will collect these tanks at the end of the 2 weeks.

If you are already receiving oxygen tanks from Health Systems, you will continue to receive them after the study. If you are already receiving oxygen tanks or other equipment from Health Systems Services or other providers, you can continue to use them after the study. However, during this study, you will be asked to only use the equipment the researchers give you.

### ***What are my responsibilities if I take part in this research?***

If you take part in this research, you will be responsible for telling the researchers about your medical history and smoking history. You will be responsible for not using oxygen while smoking, around others who smoke, or around any open flame. You will be responsible for giving researchers permission to obtain medical information about your ILD or COPD from your treating providers. This information is needed to make sure you can be in the study and that it is

safe for you to be in the study. You will be responsible for attending all study visits and completing all testing and surveys. You will be responsible for using the oxygen equipment and medical devices as instructed and to not adjust or alter equipment or settings. You will also be responsible for returning all equipment and devices at the end of the study.

### ***What happens if I say yes, but I change my mind later?***

You can leave the research at any time and it will not be held against you. If you decide to leave the research, you will be asked to notify the researchers in writing so they can arrange for you to return all the study equipment and devices. If you stop being in the research, data that was already collected may not be removed from the study database. If you agree, this data will be handled the same as research data. If you request that your data be removed from the study, then every effort will be made to securely remove your data.

### ***Is there any way being in this study could be bad for me? (Detailed Risks)***

It is possible you will have low oxygen levels with activity during this study. This will most likely happen during the 2-week period when you will be asked to not use oxygen. Low oxygen levels may cause symptoms such as shortness of breath. Prior research suggests that when symptoms from low oxygen levels occur during activity, they usually go away after a few minutes of rest. There is no evidence that brief episodes of low oxygen over the duration of this study will cause any short-term or long-term harm to you. If you have any questions about your equipment, you should contact the Primary Investigator. All participants in this study are recommended to discuss ongoing oxygen therapy with their treating providers after completion of this study.

The Oxiwear ear probe will require you to use an app on your smartphone to collect your oxygen levels. If Oxiwear measures a low oxygen level, it will vibrate and send a notification to your phone. You can check the app at any time to see your most recent oxygen level. It is possible that some low oxygen levels are not true. Poor quality of oxygen measurements can cause inaccurate levels to be measured. You will be asked to not view your oxygen levels in the Oxiwear app during this study. You will also be asked to not use any other oxygen level monitoring device during the study. If you receive repeated alerts about low oxygen levels for at least 5 minutes or have any symptoms associated with low oxygen levels (shortness of breath, chest tightness/pain, lightheadedness or dizziness) you should stop and rest for at least 5 minutes.

There is a risk that the devices you will wear may cause some skin irritation. This risk is expected to be low for the devices used in this study. If irritation does occur, it will likely resolve if you remove the device for a brief period of rest. You may also move the device to a different location, for example by putting the ear probe on your other ear or the wrist device on your other wrist.

Prolong use of oxygen therapy can cause a dry nose which can sometimes lead to a nose bleed. This risk is expected to be low for this study as you will only be wearing oxygen when you are active. If you develop a nosebleed, it should resolve by removing your oxygen and holding pressure over the bridge of your nose for several minutes.

There is a risk of falling or tripping when using oxygen equipment. This risk is expected to low for the devices used in this study. We will teach you how to use and walk with these devices safely.

As each in-person visit and during follow-up phone calls, you will be asked whether you have experienced any adverse event related to this study. You may also contact the research team at any time to report an event. The research team may also communicate with your treating provider about possible events.

We will review data collected in this study at least every 3 months. If we find that data you're your wearable devices show abnormal findings such as very high heart or very low heart rates or abnormal heart rhythms then we will notify you and your treating provider so that it can be investigated further.

Oxygen is flammable, so there is a risk of fire or burns when it is used near open flames. You will not be able to participate in this study if you currently smoke or if anyone in your household smokes. It will be important for you to not use oxygen when around those who do smoke or when around open flames such as cooking on a gas stove.

There is a small chance that someone who is not authorized could see your private study information. We are taking steps so that does not happen. More information can be found in ***What happens to the information collected for the research.***

### ***What happens to the information collected for the research?***

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. We will need to share your name, phone number, and address with Health Systems Services who will provide you with the oxygen tanks used in this study. By agreeing to participate in this study, you are giving us permission to share this information with Health Systems Services. Health Systems Services will be required to follow the same confidentiality requirements as other members of your research team.

You will be assigned a unique study number when you join this study. All data will be associated with the unique study number and not your name or other identifying information. Researchers will collect data from the oxygen equipment and medical devices used in this study. The Oxiwear device will require you to send data through an app on your smartphone. Researchers will help you set up this app and assign you with a random identifier to protect your privacy. No identifying information about you will be stored or collected from the equipment and devices used in this study. All equipment and device data collected for this study will be electronically stored in password-protected, encrypted folders on UB computers. Access to this information will be limited to members of the study team. Any hard copy files including this consent form and surveys will be stored in a locked cabinet in a secure office. Access to these hard copies will be limited to the research team. Data from the hallway walk tests and surveys will be entered into an electronic file. Once entered, these hardcopy documents will be destroyed.

Your electronic data will be kept after the study period for an indefinite period. This data may be used in future studies related to oxygen therapy in ILD and COPD. If information that identifies

you is removed from your study information, it could be used for future research studies or given to other researchers without your additional consent.

The sponsor, monitors, auditors, and the IRB will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

### ***Can I be removed from the research without my OK?***

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include results or medical information which indicate that you are not eligible for the study.

### ***What else do I need to know?***

#### **Who is paying for this research?**

This research is being funded by a National Institutes of Health (NIH)/National Center for Advancing Translational Science (NCATS) K12 career development award through the University at Buffalo Clinical and Translational Science Institute. Any excess costs are funded by the Department of Medicine in the UB Jacobs School of Medicine and Biomedical Sciences.

#### **What medical costs am I responsible for paying?**

There are no costs to you or your private or public insurance provider for participating in this study other than costs related to your travel and parking for in-person visits, the cost of data usage for uploading Oxiwear data from your smartphone app, and electrical cost for charging the oxygen equipment and wearable devices. If you already receive ambulatory oxygen therapy, you will be asked to use only the equipment provided in this study. Neither you nor your insurance company will be billed for the use of oxygen equipment used in this study. Neither you nor your private or public health insurance company will be charged for any of the tests or procedures done for this study.

#### **Who will pay for my medical care if participating in this research harms me?**

You will receive medical treatment if you are injured or become ill as a result of this study. Your doctor will explain the treatment options to you and tell you where you can get treatment. It is important that you tell the study team if you feel that taking part in this study has injured you or caused you to become ill.

UB makes no commitment to provide free medical care or payment for any unfavorable outcomes that result from your participation in this research. Medical services will be billed at the usual charge and will be your responsibility or that of your third-party payer but you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research including the University at Buffalo.

### **Will I get paid for my participation in this research?**

If you agree to take part in this research study, we will provide you with a \$50 gift card per study visit for your time. This includes \$50 for the initial visit including the hallway walk test and enrollment questionnaire, \$50 for completing the full baseline assessment (repeated hallway walk tests, symptom and quality-of-life surveys, vital signs, height/weight), and \$50 for completing each of the 3 follow-up visits. The maximum amount you may receive is \$250 for completing the study.

### **What will happen to my information and samples?**

Your de-identified information and data will be kept indefinitely and may be used in future research projects.

### **What will I be told about clinically relevant research results?**

You will not be told the results of your specific involvement in this study. We will periodically evaluate collected data for any safety issues. If this reveals any significant abnormality such as low oxygen levels at rest, persistently elevated heart rates, or heart abnormalities then we will notify you and your treating provider.

You be told oxygen concentrator setting and the oxygen tank flow rate which are sufficient in keeping your oxygen level up during the hallway walk test. You may use this information to discuss ongoing oxygen treatment with your treating provider after completion of this study.

## **HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes**

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

### **A. What individually identifiable health information will be collected about you as part of this research study?**

- Information from your full medical records: medical history, current and past medications, results of pulmonary function testing, prior chest imaging and reports including chest x-rays and CT scans, results of any previous oxygen assessments)
- New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

### **B. Who is authorized to create or provide this information for research use?**

- KALEIDA Health, Buffalo NY
- ECMC Healthcare Network, Buffalo NY
- UBMD Clinical Practice Plan(s) (identify): UBMD Internal Medicine
- General Physicians PC
- Great Lakes Integrated Network (GLIN)

- Catholic Health Network
- Roswell Park Cancer Institute
- Buffalo Medical Group
- Other(s) (identify): \_\_\_\_\_

**C. Who is authorized to receive the information from the information providers identified in (B)?**

- Principal Investigator or designee

**D. With whom may your protected health information be shared?**

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

- Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment
- The sponsor of this research study National Institutes of Health/National Center for Advancing Translational Science and the **UB Clinical and Translational Science Institute**, cooperative group, etc., or its agents
- The organization(s) responsible for administering this research **Research Foundation of SUNY**
- Health Systems Services for the purposes of providing you with the oxygen tanks that will be used in this study

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

**E. How long are the information providers listed in (B) authorized to provide your information for this research project?**

- This authorization will expire at the end of the research study. After that time, this authorization may not be used
- Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

**F. What are your rights after signing this authorization?**

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Kristopher Clark, MD  
Primary Investigator  
Buffalo General Medical Center  
100 High St, Room B-814  
Buffalo, NY 14203  
Kclark4@buffalo.edu

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

**G. What will happen if you decide not to sign this authorization?**

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

### Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

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Signature of subject

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Date

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Printed name of subject

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Signature of person obtaining consent

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Date

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Printed name of person obtaining consent

***[Check the below box and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. \*Note: you must have prior IRB approval to utilize the short form of consent documentation.]***

☐ My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

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Signature of witness to consent process

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Date

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Printed name of person witnessing consent process