Informed Consent/Authorization for Participation in Research

Title of Research Study: Structured Personalized Oxygen and Supportive Therapies for Dyspnea in Oncology (SPOT-ON) Approach for Dyspnea Treatment in Cancer Patients: A Randomized Clinical Trial

Subtitle: SPOT-ON

Study Number: 2023-0933

Principal Investigator: David Hui, MD

_____ _____
Participant's Name Medical Record Number

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 invited to take part in a research study because you have advanced cancer and are experiencing difficulty breathing (called dyspnea).

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?

Currently, there is still much debate about which of the treatments for shortness of breath are most effective for individual patients. In this study, patients will try multiple therapies to identify the best combination for relieving their shortness of breath.

The goal of this clinical research study is to learn about the effect of Structured Personalized Oxygen and Supportive Therapies for Dyspnea in Oncology (SPOT-ON) treatment on the severity of shortness of breath in patients with cancer.

This is an investigational study. SPOT-ON is an investigational approach for deciding the best shortness of breath treatment for cancer patients. Study therapy will be delivered using standard, FDA-approved devices.

The study doctor can answer questions about the SPOT-ON treatment.

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

You will receive SPOT-ON treatment for 72 hours (3 days). About 30 days after your treatment ends, the study staff will check on how you are doing.

You will be asked to work with the research team to complete the treatment and answer questionnaires.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

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

Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

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?

Taking part in this study can help provide relief for your shortness of breath. Future patients may benefit from what is learned. However, it cannot be promised that there will be any benefits to you or others from your taking part in this research.

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

Participation in research is completely voluntary. You can decide to participate, not participate, or stop participation at any time without penalty or loss of your regular benefits.

Instead of taking part in this study, you may choose to receive standard care for shortness of breath outside of this study. You may choose to receive other investigational care, if available. These alternatives have risks and benefits that may be the same or different than those in this research study. The study doctor can discuss these alternatives with you, including their possible risks and benefits.

In all cases, you will receive appropriate medical care.

Detailed Information

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

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-563-7637.

This research has been reviewed and approved by the MD Anderson Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at 713-792-6477 or IRB_Help@mdanderson.org if:

- 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 have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected about 150 people at MD Anderson will be enrolled in this research study.

What happens if I agree to be in this research?

Study Groups
If you agree to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups (SPOT-ON or SPOT-ON Waitlist) to determine when you

will start SPOT-ON treatment for your shortness of breath. You will have an equal chance (50/50) of being assigned to either group. Randomization will be completed by a computer using the secure Clinical Trial Conduct website.

You will start the SPOT-ON treatment within 3 days after you are enrolled in the study; however, the exact timing of when this treatment will start will be based on the study group you are assigned to. To minimize bias in the study, the exact timing you will receive SPOT-ON treatment will not be disclosed to you or the research coordinator doing the study assessments.

Study Treatment

During the study treatment, you will work with the healthcare team to find the best ways to reduce your shortness of breath by finding what combination of treatments work for you. You will receive education about shortness of breath by the research staff in addition to information about standard treatments or medications for your shortness of breath that would be offered by your medical team.

Regardless of which study group you are assigned to, you will start treatment within 3 days of enrollment, which may include: receiving information on breathing techniques, relaxation techniques, posture techniques, and distraction techniques, and/or trying different oxygen-based therapies, such as high-flow nasal cannula, low-flow supplemental oxygen, and non-invasive ventilation with a respiratory therapist.

High-flow nasal cannula delivers warm, humidified oxygen through a heated tube through the nostrils. Low-flow supplemental oxygen is not warmed and is delivered at a slower rate than high-flow. Non-invasive ventilation involves the delivery of oxygen into the lungs through a face or nasal mask under positive pressure, without the need for intubation.

All oxygen-based therapies are currently used in clinical care. High-flow nasal cannula and non-invasive ventilation will be delivered using an FDA-approved Hamilton C1 ventilator with commercially available accessories, including nasal masks, facial masks, and nasal cannula. This device is currently used throughout MD Anderson for routine clinical care.

If you choose to sample oxygen-based therapies, you will have the opportunity to try each of the 3 treatments for 5–10 minutes. Afterwards, you will have a say in which one(s), if any, you would like to continue using for the management of your shortness of breath over the next 72 hours.

You are not required to try any of these oxygen-based therapies if you do not want to, and you can still participate in the study if you choose not to try an oxygen-based therapy.

You will have completed the study treatment after you have completed 72 hours of SPOT-ON treatment or if you ask to be removed from the study.

Study Questionnaires
Before starting the treatment, the study staff will collect information about your demographics (such as your sex, ethnicity, and race), your cancer diagnosis, other diseases or conditions you may have, measurements related to your breathing (such as blood oxygen level and the amount of air you can inhale), medications you are receiving, other symptoms you may have, and your respiratory care goal. You will answer questionnaires about the intensity and unpleasantness of your shortness of breath, symptoms you are experiencing, and your quality of life. They will take less than 10 minutes total to complete.

Your shortness of breath and other symptoms will be assessed by the research coordinators through questionnaires that will be done over the telephone. At 24, 48, and 72 hours, you will answer the same questionnaires you answered before starting this clinical trial, as well as questionnaires about changes in your ability to breathe and your experience in the study. They will take less than 10 minutes total to complete. The study team will also ask you if you have experienced any side effects.

Follow-Up
About 30 days after your treatment ends, the study staff will call you to check on how you are doing and ask if you have experienced any side effects. The call will take about 5 minutes.

If you stop taking part in this study because of intolerable side effect(s), you will be followed until the side effect(s) get better or become stable.

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

If you take part in this research, you will be responsible for the following:
- Tell the study team about any symptoms or side effects you have.
- Follow study directions.

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

You can leave the research at any time; it will not be held against you. You may withdraw from participation in this study without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can help you safely stop study treatment. It may be dangerous to suddenly stop study treatment. The study doctor will also decide if you need to have any visits or tests to check on your health.

If you stop participating in the research study, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

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

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after the procedure, but in some cases side effects may be serious, long-lasting, or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the procedure.

Supplemental Oxygen Use Side Effects (high-flow nasal canula, non-invasive ventilation, and low-flow supplemental oxygen)

High-flow nasal canula, non-invasive ventilation, and low-flow supplemental oxygen involve delivering extra oxygen to you. The use of supplemental oxygen may cause:

• irritated or dry mouth or throat • eye irritation (possible dry eyes or painful red eyes)	• difficulty breathing • irritated or dry nose	• oxygen toxicity (possible damage to lungs, eyes, and nervous system, especially with prolonged exposure to high levels of oxygen)

There is an increased risk of fire, especially if the patient is smoking or if oxygen leaks from the delivery device and makes contact with an ignition source.

High-flow Nasal Canula Side Effects

High-flow nasal canula may cause nasal bleeding and an increased risk of infection, such as pneumonia. This infection may occur anywhere. It may become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Non-invasive Ventilation Side Effects

Non-invasive ventilation may cause the following side effects:

• discomfort from mask or skin irritation behind the ears or under the nose • difficulty tolerating the pressure support, such as air hunger, chest pain, or abdominal swelling	• increased work of breathing or airway resistance, which may lead to failure of non-invasive ventilation and need for invasive ventilation	• worsening of the underlying respiratory or cardiac condition, such as increased oxygen requirement or fluid in the lung • infection

Non-invasive ventilation may cause an increased risk of infection, such as pneumonia or sinusitis. This infection may occur anywhere. It may become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Other Risks

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

The SPOT-ON treatments offered by the respiratory therapist will be provided at no cost to you.

You and/or your insurance provider will not have to pay for certain research exams and procedures done that are covered by the study.

You and/or your insurance provider will be responsible for the costs of routine clinical services (such as diagnostic/therapeutic procedures, drugs, devices, laboratory assays,

and other services that would ordinarily be ordered for medical care, regardless of whether or not you are participating in a study). There may be extra costs that are not covered by your medical plan that you will have to pay yourself.

Taking part in this study may result in added costs to you (such as transportation, parking, meals, or unpaid leave from work). You may have to pay for medication prescribed to treat or prevent side effects, and you may have to visit the clinic/hospital more often than if you were not participating in this study.

If you have insurance, talk to your insurance provider, and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.

You may ask that a financial counselor be made available to you to talk about the costs of this study.

As compensation for your time and effort, you will receive a $50 gift card for completing the study.

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 records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

The results of this research may be published in scientific journals or presented at medical meetings. However, your identity will not be disclosed. Your name and other identifying information will be kept confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data or samples be used for future research?

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson and the National Institutes of Health, or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if the disease gets worse, if intolerable side effects occur, if you are unable to follow study directions, or if the study is stopped.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- call the study doctor (Dr. David Hui, at 832-421-4450) or 713-792-2121 (24 hours)

You will not be reimbursed for expenses or compensated financially by MD Anderson or the National Institutes of Health for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

What else do I need to know?

This research is being funded by the National Institutes of Health

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study

results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- National Institutes of Health, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)