Department of Veterans Affairs	**VA Research Consent Form**	
Title of Study	*Novel treatment of sleep apnea by upper airway and respiratory muscle training*	
Participant's Name		
Participant ID Number		**Date:**
Principal Investigator	*Abdulghani Sankari, M.D., Ph.D.*	**VAMC:** John D. Dingell VA Medical Center

You are being asked to volunteer to take part in a research study at the John D Dingell VA Medical Center. Participation in this research study is voluntary. This consent form gives you information about the study. It is important that you read and understand the information on this form.

About 100 people will take part in this study at the John D Dingell VA Medical Center.

This study is being sponsored by the VA. 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.

Please read this form and ask any questions you may have before agreeing to be in the study.

PURPOSE OF RESEARCH STUDY:
You are being asked to be in a research study of how breathing is controlled by your body during wake and sleep in individuals with spinal cord injuries because you have a spinal cord injury at the cervical, thoracic or L1-L3 spinal levels and do not require a ventilator on a regular basis. The purpose of this study is to look at the use of oropharyngeal and respiratory muscle training techniques in patients with spinal cord injuries and sleep disordered breathing to determine if they are acceptable and tolerable in the treatment of sleep disordered breathing.

STUDY PROCEDURES:
This study will involve 8 visits. The first visit (consenting visit, visit 1) will occur during the day or early evening. You will be asked to come to the lab where you will be shown the bedroom, setup and equipment and the study will be fully explained to you and this consent form reviewed. You will be given the time to ask questions and have all your questions answered before you are asked to sign this consent form. If you choose to participate in the study and sign the consent form, you will then be asked to complete questionnaires, complete a urine pregnancy test if you are a woman of childbearing age, and have your height, weight, and blood pressure measured. This visit will take approximately 2 hours and you will be compensated $25.00 for the consenting visit.

While you are in the sleep lab during visit 1, you will be equipped with a machine that will take measurements on you that night. Belts will be placed around your chest and abdomen to determine the effort you exert to breathe. A small probe will be placed on your index finger to measure oxygen saturation. Three probes will be placed on your chest to measure heart-rate activity. A small tube known as a PTAF will be inserted into the entrance of your nose to measure breathing throughout the night. The device will also record audio during the night, primarily to detect snoring. The recording will begin at your usual bedtime as provided in your initial phone interview. You will return the device to the sleep lab the next day. You will be compensated $50.00 for completion of the at-home sleep test.

Your next two visits (visits 2-3) will be sleep studies. You will be asked to restrict your sleep for the night immediately before the study date to four hours of sleep and to stay awake for at least 12 hours before each study session (no naps during the day or evening before the study). You will also be asked to finish your last meal 3 hours prior to coming in for the visits. You will be asked to come in 1-2 hours before your normal bedtime. Monitoring devices will be used during the study, which include bands placed around the neck, chest and abdomen to measure motion, wires taped to the skin to measure brain waves, eye movements, and movement, and an instrument placed on your ear, finger or forehead to measure oxygen and carbon dioxide levels in your blood. Another instrument will be placed on your finger to measure your heart rate and blood pressure through the night. During one of the two nights, you will breathe through a PTAF and we will monitor the way you sleep naturally. Before the sleep study, we will measure your lung function and perform other respiratory muscle strength tests. We will also measure tongue strength and blood pressure. For this night study, you will be compensated $50.00. During the other night study, you will breathe through a tight-fitting mask. A sticky glue may be used to fix the mask in place and prevent air leaks. During the study your mouth must be closed and/or taped to prevent air leaks. You may be asked to use Afrin nasal spray (oxymetazoline HCl) before starting the study to get rid of any nasal congestion. You may be given zolpidem (Ambien 5 or 10mg or Ambien CR 6.25 or 12.5 mg) to help you sleep. **We request that you stay in the lab for at least 8 hours after taking this drug so that its effects will wear off before you drive a vehicle or otherwise operate machinery for your safety.** A very thin flexible tube will be placed through your nose and the tip will sit in the back of your throat. A numbing medication called lidocaine will be sprayed in the nose before putting in the tube to make you more comfortable and to make the tube slide in easier. We will do trials where the pressure inside the mask will be reduced for short periods of time (1-2 breaths) until the pressure needed to cause your airway to briefly close is found. We will look at the effect of carbon dioxide on your breathing patterns during sleep. To do this, a breathing machine will be used to help you

take deeper than average breaths for short periods (1-15 min) while sleeping or we will add air with an increased concentration of carbon dioxide into the air that you will breathe for short periods (3-10 min). To look at the effect of higher than normal oxygen levels on your breathing, you will breathe air with oxygen added so that the oxygen level is about 50% (room air oxygen is approximately 21%). This visit will take approximately 7-12 hours. You will be compensated $75.00 for this night study. If we are unable to complete all the trials, we will have you come back for another night study with the same setup and complete the rest of the trials. For this visit, you will be compensated $75.00.

After you complete visit 3, if you are eligible to continue with the study, you will receive one of two exercise programs that will strengthen muscles in your face, mouth, throat, and lungs. Which exercise program you will receive will be determined randomly (like flipping a coin). You will not know what group you have been assigned to.

During visit 4, you will meet with research staff and/or a speech pathologist to learn how to do the exercises. Once you learn how to do them, the exercises will take you about 30 minutes to complete and you will be asked to do them once a day for 3 months. You will also fill out a daily log that asks how long the exercise took you to complete. You will receive $25 for this visit.

Visit 5 will be one week after visit 4. You will come back to the lab to meet with research staff to go over the exercises again to make sure you are doing them correctly and to answer any questions you have about them. You will receive $25 for this visit.

Visit 6 will be 3 weeks after visit 5 and will be a sleep study. At this visit, we will measure your lung function and other respiratory muscle strength just like we did at visits 2 and/or 3 then perform an intervention sleep study as described in visit 1. You will also complete the same questionnaires you completed during visit 1. We will go over the exercises again and answer any questions you have about them. After this visit you will be asked to continue doing the exercise program at home for 2 months. The research staff will contact you once a week by phone to see how the exercises are going and to answer any questions that you have. You will receive $150 for this visit.

Visits 7 and 8 will be 2 months after visit 6, and they will be your last visits for this study. You will come to the lab for two overnight sleep studies like those mentioned in visits 2 and 3. You will also complete the same questionnaires that you completed at visits 1 and 6, and we will measure your lung function and other respiratory muscle strength like we did in visits 2, 3 and 6. You will receive $100 for the visit in which we monitor your sleep and $225 for the visit in which we perform trials.

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Three months after visit 8, we will call you on the phone and ask you if you are still performing the exercises. We will also ask you some questions regarding your sleep patterns and fatigue levels. There is no compensation for this phone call.

RISKS:

By taking part in this study, you may experience the following risks:
Possible side effects of the topical anesthetics (lidocaine) may include: gagging, burning, or irritation of the nose and/or the throat and less likely, allergic reaction. There is also the possibility of minor skin irritation from the paste used to attach monitoring wires or devices.

Risks associated with the use of Afrin nasal spray include temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge. Frequent use may cause nasal congestion to happen more often or get worse.

For the study done the first night, you may awaken from the intervention (lowering the mask pressure) and could have trouble falling back to sleep or not feel as well rested the next day if awakening happens frequently during the night study. The risk associated when the breathing machine assists your breathing is that you may wake up with the change in air pressure inside your mask and have trouble falling back to sleep or not feel well rested the next day if awakening happens frequently throughout the night study.

The possible side effects of receiving Ambien without a full night's sleep include an unsteady feeling, sleepiness, headache, and dizziness which are all temporary and subside once the drug clears from your system (about 8 hours after initial administration). To avoid any drowsiness-related accidents, you will be asked to stay in the research laboratory for at least 8 hours after you have taken the drug.

The risks associated with limiting your sleep to less than 4 hours the night before a sleep study, are that you may feel tired or drowsy during the day and have a slower response time. This may put you at a greater risk for motor vehicle or work-related accidents. **Please do not drive if you are feeling sleepy or work with machinery that may put you at risk until you are well-rested. If you feel too tired to drive to the lab for your sleep study,**

please have someone drive you. You may also feel sleepy the morning after a night study if you were unable to sleep well or to sleep as long as you normally would. Please arrange for someone to pick you up from the lab the morning after the study and drive you home for your safety.

There is also a very small risk of a mild nose bleed or soreness due to insertion of the thin tube in your nose. This will be lessened by using lidocaine which numbs your nose and throat and helps the tube slide in easier.

There may be unknown risks to women who are or may become pregnant, to unborn babies, and to nursing infants. Therefore, to take part in this study, a medically acceptable form of birth control is required—for both male and female participants. Medically acceptable birth control may include the following methods: barrier protection—such as condoms, intrauterine devices (IUD), abstinence (not having sex), etc. Oral contraceptives may be used but should not be the only means of protection. No birth control method completely eliminates the risk of pregnancy. You should inform the study doctor (PI) immediately if you or your partner intends to get pregnant or if you or your partner should become pregnant while participating in this research study, so that your choices and options can be explored and discussed.

There may also be risks involved from taking part in this study that are not known to researchers at this time.

BENEFITS:
As a participant in this research study, there will be no direct benefit for you; however, information from this study may benefit other people with similar health issues now or in the future.

STUDY COSTS:
Medical care that is part of this research project will be provided at no cost to you. If you are a participant with a spinal cord injury, the lab will provide medical transportation to and from study visits at no cost to you. In the rare instance that you should have any transportation costs related to your study visits, you will be paid back for your expense.

ALTERNATE COURSES OF ACTION:
The alternative to participating in this research study is not participating in the study.

STATEMENT OF RESEARCH RESULTS:
When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

COMPENSATION:
For taking part in this research study, you will be paid for your time and effort. *The IRS requires that compensation greater than or equal to $600 per calendar year be reported to the IRS - refer to http://www.irs.gov/pub/irs-pdf/i1099msc.pdf*

Consenting Visit	$25
Exercise Training Session	$25
Exercise Follow-up Session	$25
Minimum payment	$25
Baseline Take-Home Sleep Test	$50
Baseline In-lab Screening Sleep Study	$50
Baseline Intervention Night Study	$75
One Month Intervention Night Study	$150
Three Month In-lab Screening Sleep Study	$100
Three Month Intervention Night Study	$225
If caregiver needed for sleep study	$50

CONFIDENTIALITY:
As part of standard care, a polysomnogram, which is a test conducted to study your sleep patterns, record both your sleep study along with audio and video recording. This is to ensure your safety during your sleep study. Video and Audio recording help to confirm your body position along with monitor you for respiratory events during your study. Audio and Video recordings will only be used for clinical purposes to assist in evaluating your

sleep. Any recordings obtained during the course of your sleep study will remain confidential and will only be accessed by the physician and designated personnel.

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. Federal agencies including, but not limited to, the FDA, OHRP, ORO, and the VA Office of the Inspector General (OIG) may have access to the records. Your research records will be kept in a locked cabinet in the locked research lab.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION
The investigator reserves the right to terminate your participation if, in the judgment of the investigator, your continued participation represents a potential for harm or if you are no longer a good candidate for this study.

RESEARCH PARTICIPANT'S RIGHTS:
You have read each page of this consent form or each page has been read to you. A member of the research team has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been told that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of your rights. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

If you have any questions, concerns or complaints about this study now or in the future, you may contact Dr. Sankari or one of his research team members at the following phone number (313) 576-3548. If you have questions or concerns about your rights as a research participant or the validity of this study, the Chair of the Investigational Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research team, you may call the Research Compliance Officer at (313) 576-4467 to ask questions or voice concerns or complaints or you may call the Patient Advocate at (313) 576-1000, ext. 65158.

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Department of Veterans Affairs	**VA Research Consent Form**	
Title of Study	*Novel treatment of sleep apnea by upper airway and respiratory muscle training*	
Participant's Name		
Participant ID Number		**Date:**
Principal Investigator	*Abdulghani Sankari, M.D., Ph.D.*	**VAMC:** John D. Dingell VA Medical Center

The VA will provide necessary medical treatment should you be injured by participation in this study or have side effects that need medical treatment. You will be treated for the injury or side effect at no cost to you, but no provisions have been made for additional compensation. No reimbursement, compensation or free medical care is offered by Wayne State University. You may be among the veterans required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Your signature on this form indicates that you have had this research explained to you and your questions about it answered, and you voluntarily consent to participate in this study. You will receive a signed copy of this consent form.

x	x	x
Research Participant's Signature	Date	Time

x	x	x
Signature of person obtaining consent (Study personnel must be approved by IRB.)	(Print Name)	Date

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WAYNE STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD

Department of Veterans Affairs

Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

VA Facility (Name and Address):
John D. Dingell VA Medical Center
4646 John R St.
Detroit, MI 48201

VA Principal Investigator (PI):	**PI Contact Information:**
Abdulghani Sankari, M.D., Ph.D.	John D. Dingell Medical Center Research 11-R, Room C3411 4646 John R St Detroit, MI 48201

Study Title:
Novel treatment of sleep apnea by upper airway and respiratory muscle training

Purpose of Study:

You are being asked to be in a research study of how breathing is controlled by your body during wake and sleep in individuals with spinal cord injuries because you have a spinal cord injury at the cervical, thoracic or L1-L3 spinal levels and do not require a ventilator on a regular basis. The purpose of this study is to look at the use of oropharyngeal and respiratory muscle training techniques in patients with spinal cord injuries and sleep disordered breathing to determine if they are acceptable and tolerable in the treatment of sleep disordered breathing.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

☒ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☐ Specific information concerning:

☐ alcohol abuse ☐ drug abuse ☐ sickle cell anemia ☐ HIV

☒ Demographic Information such as name, age, race

☐ Billing or Financial Records

☒ Photographs, Digital Images, Video, or Audio Recordings

☒ Questionnaire, Survey, and/or Subject Diary

☒ Other as described: Banking Information (Optional). Street Address, City, State, and Zip Code

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☒ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☒ Non-VA Institutional Review Board (IRB) at Wayne State University
who will monitor the study

☐ Study Sponsor/Funding Source: _____
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☐ Academic Affiliate (institution/name/employee/department):
A relationship with VA in the performance of this study

☒ Compliance and Safety Monitors: VA Research Compliance and Safety Officers
Advises the Sponsor or PI regarding the continuing safety of this study

☒ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):
FDA, OHRP, ORD, ORO

☐ A Non-Profit Corporation (name and specific purpose):

☒ Other (e.g. name of contractor and specific purpose):
R & R Transportation and Efficient Transportation

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you

☐ will have access to your research related health records

☒ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

John D. Dingell Medical Center
Research 11-R, Room C3411
4646 John R St
Detroit, MI 48201

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☐ Expire at the end of this research study

☒ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

_____ _____

Signature of Research Subject Date

_____ _____

Signature of Legal Representative (if applicable) Date

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

_____

Name of Legal Representative (please print)