RUTGERS
Robert Wood Johnson
Medical School

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Obstructive Sleep Apnea in World Trade Center (WTC) Responders: Role of Nasal Pathology **Principal Investigator:** Jag Sunderram, MD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

SPONSOR OF THE STUDY: NIOSH (National Institute of Occupational Safety and Health).

NIOSH is the sponsor of this research study. The study doctor is being paid to conduct this study according to a budget that will cover the costs of the study. The costs that are usually covered include things such as: physical examinations, laboratory tests required by the study, and the costs of collecting all of the information required by the study.

Why is this study being done?

The study is being done to see if there is a relationship between sleep apnea (problems with breathing during sleep) and problems with the upper airway (the nose and throat). The study will look at this relationship in WTC responders. The dust exposures from WTC may increase the problems in the upper airway and lead to sleep apnea. For people who have sleep apnea, the study will also test two treatment options. The study will determine if one treatment option works better for people with specific upper airway problems.

Why have you been asked to take part in this study?

You have been asked to take part in the study because you are a member of the WTCHP (World Trade Center Health Program) at EOHSI (the Environmental and Occupational Health Sciences Institute) and have consented to be contacted for future studies.

Who may take part in this study? And who may not?

Adults who are part of the WTCHP may take part in the study.

The following people may not participate in the study:

- People who had a history of habitual snoring (snoring several nights a week) prior to WTC
- People who have skeletal alterations (deformities in the bones of the face) that may affect the upper airway or a perforated septum (hole in the nose)
- People with unstable chronic medical conditions such as congestive heart failure or stroke
- Women who are pregnant or intend to become pregnant in the study period
- People who had their first visit to the WTCHP after February 1, 2013 or who do not have information regarding snoring prior to September 11, 2001 and who currently snore.
- People who are being treated for sleep apnea by either:
    - Had upper airway surgery
    - Are currently (within the last 2 months) using either a device placed in the mouth (like a dental guard or mandibular splint) or CPAP (Continuous Positive Airway Pressure; a device that blows air to keep the airways open during sleep).

How long will the study take and how many subjects will participate?

The study will be conducted over a four year period. A total of 500 subjects from the EOSHI WTCHP will participate. The study is also being done at New York University and Mt. Sinai School of Medicine and 500 subjects are expected to participate at those sites as well.

Your participation will involve 1-2 clinic visits which will take place over a 6 month period.

What will you be asked to do if you take part in this research study?

The study has two phases. All study participants will be asked to complete Phase 1. Only those study participants who have sleep apnea will be asked to complete Phase 2.

Phase 1: Diagnosis of Upper Airway Problems and Sleep Apena

Clinic visit (approximately 1.5 hours):

- At your first clinic visit, you will be asked to fill out four questionnaires about your nasal symptoms, sleeping habits, daytime sleepiness and problems with sleeping. Together, the questionnaires will take approximately 20 minutes.

- You will have a brief physical exam including measuring your height and weight and having your nose and mouth examined by a research assistant. This exam will collect research data. It is not meant to diagnose any medical conditions.
- You will have a measurement of nasal resistance (rhinomanometry) which is a measurement of how air flows through the passages of the nose. To measure the air flow, a small tube is held in place in your nostril using tape over the nostril and a mask is placed on your nose while you breathe normally. The measurement will be made first while you are sitting, then again while you are lying down. You will then be asked to use a nasal spray for decongestion. The same measurements, sitting up and lying down, will be repeated.
- You will also have a nasal lavage. Using a saline solution, you will be asked to spray a nostril 5 times, then gently exhale the fluid into a specimen cup. This procedure will be repeated at least 8 times in each nostril. You may be asked to do it additional times (up to 16 in each nostril) to collect enough fluid for the sample.
- After your exam, you will be given a device (such as the ARES Unicorder) to take home to measure your breathing during sleep. The study investigator will show you how to use this device.

Home monitoring (2 nights):
You will be asked to do the home monitoring for two nights. You will be given two devices – an ARES monitor and a wrist pulse oximeter. The ARES monitor is worn on the forehead with oxygen tubes placed in the nose. The oximeter has two parts: a sensor to place on your index finger and a recorder to wear on your wrist like a watch. You will wear the devices while sleeping. The devices measure and record your oxygen level, pulse, airflow through the nose, head movement, and head position while you sleep. You will take the devices off in the morning once you wake up and repeat the procedure for a second night. After you do the home monitoring, you will be asked to mail back the devices.

The study doctor will look at the monitoring results. If you do not have sleep apnea, you will be sent a letter with the result and your participation in the study is finished. If you do have sleep apnea, you will be contacted by a study investigator. You will be asked to come for a second study visit. If you cannot be reached by phone, a letter with your results will be sent.

Phase 2: Treatment for participants with sleep apnea:

Clinic visit (approximately 1 hour):
The second clinic visit will take place within 6 months of your home monitoring. If more than 6 months have passed since your home monitoring, you will be asked to repeat all the activities in the first study visit (including questionniares, physical exam, measurement of nasal resistance, nasal lavage, and home sleep monitoring).

At the second clinic visit (only for those diagnosed with sleep apnea), you will meet with the study doctor or another study investigator. The study investigator will discuss the diagnosis and answer your questions. The study investigator will show you a device used to treat people with sleep apnea. This device, CPAP (Continuous Positive Airway Pressure), is a machine with a breathing mask people wear during sleep. The study investigator will fit the mask to you and

show you how to use the machine. If during the course of treatment, you have any problems with your machine or mask, you may be asked to come back to the clinic for an additional check or replacement mask.

Home treatment (approximately 2 months):
The CPAP device will wirelessly transmit your breathing information to the sleep center. For the trial period (at least 2 nights) a computer inside the CPAP machine will change the pressure level that is required to treat your apnea. After this trial period, if you use CPAP regularly, the machine will set a fixed pressure. Otherwise, treatment using changing pressure will continue. A study investigator will check the data remotely to confirm that the CPAP is operating properly. At times, either the CPAP machine or modem may fail to transmit your data. This may happen to approximately 5-10% of the users. If this happens, you will be contacted by a study investigator to resolve the problem. You may be given a new CPAP machine or modem. This instrument failure may extend your treatment period by up to 1 month.

In some cases (expected to be <5%), people receiving CPAP may continue to show problems breathing during sleep. This may be caused by other health problems. If the study investigator sees these problems, you will be contacted. The investigator may remove you from the study and advise you to consult your physician. Your physician may want to follow-up with an overnight sleep study in a clinic.
You will then be asked to use the CPAP device for the next two months. These two months will not include periods where you are unable or unwilling to use CPAP during travel or illness. The use of the CPAP device may also last for more than 2 months if we are unable to contact you after a treatment period or in cases of instrument failure. The CPAP machine has two ways of operating, called treatment modes. One mode has constant pressure and the other mode has variable pressure ($CPAP_{Flex}$). Over the next two months, you will try both modes. Both CPAP modes will treat your sleep apnea but you may perceive slight differences in comfort.

- Month 1: You will be assigned one of the treatment modes by chance. You and the investigators will not be told which of the two modes you are using first. You will be asked to use the CPAP machine every night for one month. During the first two weeks of treatment, the research coordinator will call you each week to discuss any problems or questions you have about using the CPAP device. After one month you will be called and asked about your satisfaction with the treatment. The call should take less than 5 minutes. You will also be asked to complete two questionnaires about your sleep symptoms and return them by mail. The questionnaires should take approximately 20 minutes to complete at home.
- Month 2: After you are called and you complete the telephone satisfaction questionnaire, you will be switched to the other treatment mode. You do not have to bring the CPAP machine in for the switch. The switch will be done remotely. After the second month, you will be asked again about your satisfaction with the treatment. The call should take less than 5 minutes. You will also be asked to complete additional questionnaires and return them by mail. The questionnaires should take approximately 20 minutes to complete at home. If you do not wish to keep the CPAP machine, you will be asked to make an appointment to return it to the sleep center or to return it by mail.

After completing the CPAP trial, you will be asked to return the modem on the CPAP machine, either in person or by mail. If you choose to return the modem in person, you will be asked to

provide another nasal lavage sample. The purpose of this second sample is to see if CPAP use causes changes in the analysis. You will be mailed a report of the treatment pressures used during the treatment phase. If you wish to continue to use CPAP to treat your sleep apnea, you will be encouraged to share these treatment pressures with your physician.

What are the risks and/or discomforts you might experience if you take part in this study?

The following are risks and discomforts that you may experience during your participation in this research study.

Rhinomanometry: There are no known risks.

Nasal Lavage: you may experience some minor discomfort, irritation, or nosebleed from the nasal washings. You will be trained in all procedures before exposures to assure comfort with the procedures.

Monitor Sleep Breathing with an ARES Unicorder: participants rarely develop reddening of the skin on the forehead where the oximeter (device to measure how much oxygen is in your blood) is placed. This usually disappears within a few hours. You may also experience a slight discomfort due to the pressure exerted by the strap. The elastic strap is adjustable and it may be loosened it if feels too tight. In rare cases (<0.5%), people may have a minor skin allergy to the strap material. If you think you are having a skin reaction, you should stop using the ARES.

CPAP: There are no known risks of this treatment other than the discomfort of sleeping with a mask and mild dryness or stuffiness of your nose which occurs in some individuals. This may affect the restfulness of your sleep. You will be fitted with either a nasal mask, pillows that fit within the nostril, or a mask that covers the mouth and nose (full face mask). The fitting will determine which mask fits you the best. In addition you will be given a machine with a capability of heated humidification that will minimize dryness or stuffiness of the nose. These measures will maximize your comfort. Please be mindful when you are adjusting your mask that your mask should be snug but not uncomfortable as this may cause skin irritation.

While you are on CPAP you may continue to experience sleepiness symptoms for some time and will need to exercise care while driving or performing other potentially hazardous activities that may expose you or others to risk of injury. If you are experiencing symptoms that concern you, you should discuss them with a physician. You may call your personal physician or, as a WTCHP member, Dr. Iris Udasin at 848-445-6160, or you may call the study doctor, Dr. Jag Sunderram at 732-235-7038.

Are there any benefits for you if you choose to take part in this research study?

If you do not have sleep apnea there is no direct benefit to you expected from your participation in this study. It is hoped the knowledge gained will be of benefit to others in the future. However, if you are diagnosed with sleep apnea this research study includes procedures that may change the treatment you would otherwise receive. You will be given a copy of the results of the sleep study, including the results of the CPAP treatment. If you wish, you may share the results

of the sleep study with your physician. We hope knowledge gained will be of benefit to you.

What are your alternatives if you don't want to take part in this study?

You do not have to take part in this study to remain part of the WTCHP. Your treatment in the WTCHP will remain the same whether or not you take part in this study.

If you have sleep apnea or are having other health problems, you do not have to join this study for treatment. You can seek diagnosis or treatment as part of the WTCHP and not be in the study. You can also seek diagnosis or treatment with physicians outside the WTCHP.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

There is no cost to participate in the study.

Will you be paid to take part in this study?

All subjects who complete the assessment for sleep apnea will receive $100. The assessment includes the questionnaires and exams in the first clinic visit and the two-night home monitoring.

Those subjects who have sleep apnea and participate in the CPAP evaluation will be permitted to keep the CPAP machine, if desired.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. All your study research records will be coded with an ID number. The research coordinator will store any written records with your name and contact information in a locked cabinet in a private office. The research coordinator will keep the link between your identity and the study ID in a password-protected file on a password-protected computer. Your contact information will be used to contact you for study appointments and to monitor your progress in the study.

The results of the sleep apnea monitoring will be mailed to you directly. You may choose to share them with your physician. If you wish to share the results of the study with the WTCHP clinic, you will be asked to sign an authorization form. The study investigators will then give the results to the clinic. You are not required to share the results with the WTCHP clinic. You may still be part of the study if you do not want the results to be shared with the clinic.

A description of this clinical trial will be available on 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 website at any time.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Sunderram, Medical Education Building (MEB) Room 574, 1 Robert Wood Johnson Place, New Brunswick, NJ 08901.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Dr. Jag Sunderram
Department of Medicine
732-235-7038

If you have any questions about your rights as a research subject, you can call:

IRB Director, New Brunswick/Piscataway
(732)-235-9806

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization (permission). If you sign this consent form, it will provide that authorization. The next few paragraphs tell you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization and informed consent form as required or allowed by law. Because we are committed to protecting your health information, some of the paragraphs that follow repeat what we described to you earlier in this consent form about what information we will collect about you, how we will use it, when or if it will be shared with others, and the

measures we will take to protect your privacy and the confidentiality of your personal information.

Please read this authorization section and the consent form carefully. Ask questions if anything is not understandable to you.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The study is being done to see if there is a relationship between problems with the nose and throat and sleep apnea (problems with breathing during sleep) in WTC responders. For those study participants who have sleep apnea, the study will test two different types of treatment. The study will determine if one treatment works better for people with certain nose problems. Your medical records from your first visit to the WTC Health Program will be checked to see if you have reported any problems that may be related to sleep apnea, including a diagnosis of PTSD (post-traumatic stress disorder) or GERD (gastroesophogeal reflux disease), nasal complaints, problems breathing or sleeping, and your snoring history. Your WTC exposure, including all the responses to the Exposure Assessment Questionnaire (EAQ) you completed on the first visit, will also be abstracted. The EAQ collected information on your WTC work/volunteer experiences including the dates, hours, locations, and conditions of your work. It also collected information on your use of respiratory protection. We will also check the records from that visit for your height, weight, and blood pressure.

The data we collect from your medical record will be coded by a study ID number. Your name, address, or other identifier will not be used. The data, without any identifiers, may be submitted to the sponsor of the study (the National Institute of Occupational Health and Safety). The summary data will be published in the medical literature and posted on ClinicalTrials.gov. You will not be identified in the results.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study and receive any research-related products. However, signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke my authorization or withdraw my information later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your information. Therefore, you should be aware that the researchers may continue to use and disclose the health information that was provided before you withdrew your authorization if necessary to maintain integrity of the research or if the data had already been stripped of all identifiers.

If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you may do so in writing by contacting Dr. Sunderram, Medical Education Building (MEB) Room 574, 1 Robert Wood Johnson Place, New Brunswick, NJ 08901.

What personal information will be used or disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, all information about your weight, information related to nasal, breathing, or sleeping problems, including a history of snoring.

Who may use or disclose the information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Rutgers Institutional Review Board
- Dr. Sunderram
- The research team

Who may receive/use the information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services.
- The National Institute of Occupational Health and Safety
- Collaborators at the New York University School of Medicine

Your information may be re-disclosed (shared) by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

There is no set date at which your authorization will expire. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Will access to my research study record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. You will be given the results of the home sleep monitoring once they have been analyzed. You may choose to share the results with your physician.

AGREEMENT TO PARTICIPATE

Please initial each one of the following sentences that applies:

_____ I agree to be contacted by the investigators for future research studies about sleep.

_____I do not agree to be contacted by the investigators for future research studies about sleep.

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____