Procedures/Risks: pulmonology, sleep, critical care

Bronchoscopy (and bronchoaveolar lavage)

Purpose: The purpose of the bronchoscopy is to collect cells and fluid from the lung, so that information can be gained about how the lungs...[may be associated with/or affected by...]. Bronchoscopy is a diagnostic procedure used to examine the major airpassages of the lungs. It is done so that doctors can look inside of your lungs.

Procedure: You will be asked to undergo measurements of how your lung functions. This procedure, called a bronchoscopy involves insertion of a small catheter through your nose and into your esophagus. You will then take a deep breath and exhale slowly. Measurements will be recorded through the catheter. Prior to insertion of the catheter, your nose and throat will be numbed with a local anesthetic (lidocaine).

Procedure: The doctor will insert the bronchoscope through your nose or mouth and through your windpipe into your lungs. A bronchoscope is a flexible tube about the width of a pencil. Bronchoscopy with alveolar lavage (a "washing" of the lung airways) is a procedure designed to collect samples of cells from your lung.

Before the procedure begins, you will receive medication that will help you relax and reduce any coughing or irritation. An intravenous catheter ("IV" line, a small, soft, plastic tube) will be placed into a vein in your arm or hand. This "IV" line will be removed at the end of the procedure. At this point, additional sedative medication may be given through the IV. You will be offered an intravenous injection (shot) of a medication which will reduce or eliminate any pain that you may feel during the procedure. In addition, the medication may make you sleepy. Pain relief medications are routinely used before diagnostic tests. You also will be connected to a heart and blood pressure monitor. Monitoring of your heart activity (electrocardiogram, EKG), pulse oximetry (a clip on the finger that tells us how much oxygen is in your blood) and breathing is performed continuously throughout the test. In the case of an emergency, fully trained doctors and all necessary medications and emergency equipment are immediately available.

This procedure involves taking a soft, small, flexible, fiber optic bronchoscope (a thin black tube that is about the same size and flexibility of a lamp cord) and inserting it through your mouth or nose. After the tube is passed through your mouth or nose, it goes through your vocal cords to your windpipe and then into your lungs. When the tube passes through your vocal cords, you may feel like you cannot catch your breath. This feeling is not unusual and is temporary. Your physician will stop to let you catch your breath before continuing the procedure. During this procedure, the doctor performing the bronchoscopy will look through this fiber optic (a bundle of very small wires that light goes through) scope to examine your lungs, and to make sure that the scope is placed in the correct area of your lung. During the procedure medication will be administered through the tube to help relieve any coughing. By using a nebulizer (a piece of equipment that gives out a very fine spray), you will inhale numbing medication into your mouth and airways to decrease any discomfort and to decrease any cough that you might experience

from the bronchoscopy. You can help with the procedure by taking slow, shallow breaths through your mouth. Try not to talk while the tube is in your lungs. Talking can make you hoarse or give you a sore throat.

The bronchoscopy will be moved around in order to wash your airways and collect cells from your breathing passages (alveolar lavage). The bronchoscope will be moved into a specific airway of your right lung and a small amount of sterile salt water (approximately 1 ½ Tablespoons) will be placed in your lung and immediately suctioned back out, washing off cells lining the airways; this solution will be injected four times. A portion of your left lung then will be washed in a similar fashion. The entire procedure will take from 30-60 minutes.

Risks: It is possible that you will experience the following risks and discomforts: cough, sore nose, throat, and hoarseness for 2 to 4 hours after the procedure; or an adverse reaction to the numbing medication (lidocaine).

Risks: The bronchoscopy procedure may cause you to have a sore throat, a sore nose, hoarseness, or cough. If you cough during the procedure (bronchoscopy), then some medication may be given to you for you to be able to stop coughing as well as to help relieve any discomfort that you may be having. You may also experience vocal cord spasms, spasms of the passages that lead into the lungs, or lightheadedness. Other rare but serious complications that have occurred include lowering of blood pressure, difficulty breathing, bleeding, and/or a temporary change in heart rhythm. You will be asked to remain in the laboratory for up to 3 hours after the test for observation- for your own safety. You may also experience a slight fever; it may return to normal within a few hours or you may take aspirin or acetaminophen. As always, please notify a member of the research team if you do take any other medication(s) while you are in the study.

Rarely, a respiratory infection, collapse of the washed area of the lung(s) might occur. If they do occur, then contact the researchers in order to be treated.

Continuous Positive Airway Pressure (CPAP)

Procedure: The CPAP device is typically used for treating sleep apnea [in the outpatient setting/while you are at home]. This device delivers positive pressure to you through a nasal (nose) or full-face mask. The positive pressure prevents the collapse and obstruction of the breathing passages that is typical for people with sleep apnea. This treatment is worn nightly while sleeping and is to help provide individuals with the ability to obtain healthy restful sleep nightly when it is worn.

Risk: You may experience discomfort in the fitting of the mask, dryness in your nose and sinuses (infection of the sinuses), or claustrophobia (the fear of closeness). Careful sizing and fitting of the mask should decrease the likelihood of these problems occurring.

Eucapnic Voluntary Hyperventilation (EVH)

Procedure: Eucapnic Voluntary Hyperventilation (EVH) is a lung test that requires you to breathe approximately thirty times per minute for six minutes while breathing a gas mixture that

will help prevent you from becoming dizzy. Then for up to twenty minutes, you will have lung function measured with **spirometry. [see 'spiromter' below]**

Risks: EVH can occasionally cause shortness of breath, coughing, chest tightness, lightheadedness, wheezing or headache. Usually these symptoms are mild. If there is a more severe reaction, you will be immediately treated with medication (such as albuterol which is a short acting medicine that opens narrow airways) and oxygen as is appropriate. Also, you will be asked to stay in the area until lung function returns close to the level of breathing recorded when you started the test. The likelihood of this test causing a severe reaction is very low.

HRCT (high resolution computer tomography)

Procedure: You will undergo a chest HRCT (high-resolution computer tomography, imaging by sections or sectioning). The HRCT scan is a procedure that uses radiation, like x-rays which will provide a detailed assessment of your lung tissue. This part of the research takes about an hour which includes prep-time but the actual procedure takes only about 5 minutes.

Risks: The HRCT scan will require you to lie still within a confined space for about 5 minutes. This may be uncomfortable. The total amount of time for this part of the research is approximately one hour. There is a risk of radiation exposure from a HRCT scan. This is approximately equivalent to the naturally occurring background radiation exposure that would occur from living in Columbus, Ohio for 3 years.

Peak Flow Meter

Procedure: You will be given a **peak flow meter** (a device into which you blow into as hard as you can). Peak flow meters test how well you can breathe. To use the meter, you need to take a deep breath and blow as hard as possible into the device. You also will be shown how to use the peak flow meter and how to read the meter, and where to record the results. [You will need to use the peak flow meter X times every morning and record the highest reading on an asthma diary card. If you cannot use the peak flow meter, you cannot join this study.] *Risks:* Asthma patients routinely use peak flow meters to see how their lungs are working. There is little risk from using a peak flow meter. Some people may have some chest soreness from blowing out hard, or may become light-headed if they use it standing up. The chest soreness usually goes away by itself, but can be relieved with over-the-counter pain relievers (aspirin, Tylenol)*. If you do get light-headed, you should perform the peak flow measurement while seated.

*Always check with the researchers about taking any medications (either prescription or overthe-counter), before you take it.

Pulmonary Function Testing

Procedure: A respiratory therapist will use a hand-held device to record how much air you can breathe into your lungs and how forcefully you can blow air out of your lungs. This will take approximately 15 minutes.

Procedure: You will be asked to complete pulmonary function tests (PFTs) which involve taking deep breaths and blowing all of your air out into a machine that measures your lung capacity and air flow. The pulmonary function tests (PFT) are done to determine the overall health of your lungs and to determine if there is any early lung damage.

The pulmonary function tests will include **spirometry** which involves taking deep breaths and blowing all of your air out into a machine that measures your lung capacity and air flow. Your total lung volume will be measured by having you make brief panting maneuvers into a mouthpiece. You will also do a test that requires you to hold your breath for 10 seconds.

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Risks: Pulmonary Function Tests involve forceful respiratory maneuvers. Occasionally people develop light-headedness during the procedures or soreness of the chest for a few days. You will be seated during the breathing studies to minimize the possibility of lightheadedness or fainting.

Spirometry

Procedure: During this study, a lung function test (spirometry) will be done. This test measures how well you are breathing. For this procedure you will wear a nose clip and breathe out has hard as possible. [You will be asked to do a breathing test twice during each office visit, one before and one after breathing in a medicine called a bronchodilator. A bronchodilator medicine opens the lungs as much as possible.] Depending on how much your lung function changes after the bronchodilation (i.e., the structures to the lungs are opened wider), you will asked to perform a <u>Methacholine Challenge</u> test. You will be asked to do this if my lung function does not increase enough after the bronchodilator. The methacholine test measures how your airway passages respond to methacholine. Methacholine is a chemical that may make your airways get smaller. Each time you get a dose of methacholine, you will perform a lung function test to see if there is any difference in your breathing. A dose of methacholine can be given up to 10 times. During this test, if your ability to blow out as hard as you can decreases by 20% or other symptoms develops, the test is stopped. This is a routine test done to determine the severity of a person's asthma.

Risks: There is little risk from completing a lung function test Some people may have some chest soreness, light-headedness, or dizziness from blowing has hard as possible into the machine. Chest soreness usually goes away by itself, but can be relieved with over-the-counter pain relievers like Tylenol*.

*Always check with the researchers about taking any medications 9either prescription or overthe-counter), before you take it.

<u>Methacholine Challenge test:</u> The inhaled mist can occasionally cause shortness of breath, coughing, chest tightness, wheezing or headache. Usually these symptoms are mild. If there is a more severe reaction, you will be immediately treated with medications and oxygen as is appropriate. Also you would then be instructed to stay in the area until your lung function returns close to the level of breathing recorded when you started the test.

Sputum test (induced)

Procedure: For the sputum test, you will breathe in a mist of salty water and will be asked to cough and spit into a cup. The whole procedure will take about 12 minutes during which time you will be closely monitored by trained staff.

Risks: The inhaled salty mist can occasionally cause shortness of breath, coughing, or wheezing. Usually these symptoms are mild. If there is a more severe reaction, you will be immediately treated with medications and oxygen. You will be closely monitored during this procedure. Also you will be asked to stay until your lung function returns close to the level of breathing recorded when you started the test.

Stardust Monitoring:

Procedure: The Stardust Monitor is a small and lightweight sleep recorder that is worn on your chest. It records breathing, heart rate, and oxygen levels while you sleep.

Risk: A mild electric shock may be felt from the Stardust Monitor if the device is worn in the shower or if the wires are not properly placed and/or may become entangled. These risks are not likely when the device is worn properly, and when placed and removed by a trained health care professional. No other risks are foreseen in the use of this device.

Vital capacity testing

Procedure: Vital capacity testing measures the maximum amount of air you can exhale following a deep breath. For this test, you will be asked to hold a mouthpiece in your mouth, breathe in deeply, and breathe out as long and as hard as you can.