

Consent for Commonly Performed Procedures in the Critical Care Units

I, the undersigned, understand that the intensive and intermediate care units ("critical care units") are places where seriously ill patients are cared for by specially trained staff. The critical care staff works closely together as a team to provide the best possible care. The critical care team uses a number of specialized machines and devices, called monitors, to frequently check the heartbeat, blood pressure, and breathing. Machines that help the patient breathe, called mechanical ventilators, may also be used.

I have been informed that patients in the critical care units often undergo certain medical procedures and/or treatments, either to help determine what is wrong, or to relieve symptoms or resolve problems.

I understand that some of these procedures may be performed more than once during a patient's admission. These commonly performed procedures, their use in diagnosis and treatment, as well as the substantial risks and possible complications involved, have been explained to me by Dr.______.

I have also read, or had read to me, the information sheet entitled "Commonly Performed Procedures and Related Complications," a copy of which is attached to this form and which briefly describes each of these commonly performed procedures, and their substantial risks, potential benefits and medically reasonable alternative treatments.

I have had an opportunity to ask questions of Dr._____regarding the commonly performed procedures and I have had all my questions answered to my satisfaction.

I understand the potential benefits and drawbacks, potential problems related to recuperation, the likelihood of success, the possible results of non-treatment, and any medically reasonable alternatives associated with these commonly performed procedures.

I understand that the information I have received about risks is not exhaustive, and there may be other, more remote risks. I have received no guarantees from anyone regarding the results that may be obtained from any of these treatments or procedures.

_____, consent to the treatments and/or procedures indicated by my initials below,

Name of Person Consenting

I.

which in the judgment of my critical care unit's physicians may be considered necessary or advisable for

_____'s diagnosis or treatment, and which may be performed by any of the critical

Patient's Name

care unit's physicians and their associates and assistants (including resident physicians). I understand that this consent will be considered valid for my/the patient's critical care unit admission up to 60 days, and that I may at any time withdraw my consent to any treatment or procedure.

I also understand that a refusal to consent to any of these procedures may have a serious adverse impact on my health and/or ability to recuperate.

Procedures	Initial	Procedures	Initial	
	(of patient or representative)		(of patient or representative)	
Arterial Line Insertion		Sedation, Maintenance or Procedural		
Pulmonary Artery Catheter Placement		Intubation & Mechanical Ventilation		
Central Venous Line Insertion		Bronchoscopy		
Peripherally Inserted Central Catheter		Chest Tube Insertion		
Transesophageal Echocardiogram		Temporary Dialysis Catheter Insertion		

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Anesthesia Risks for Young Children and During the Third Trimester of Pregnancy

I (we) have been informed of the potential adverse effect of anesthesia in young children especially for procedures that may last longer than 3 hours or if multiple procedures are required. I have been informed that the use of general anesthetic and sedation drugs in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains.

I have received the FDA Drug Safety Communication bulletin detailing the risks of general anesthesia on brain development in children under the age of 3 years or in third trimester pregnant women.

() Yes () Not Applicable

I have explained the procedure/treatment, including anticipated benefits, significant risks and alternative therapies to the patient or the patient's authorized representative.

		A.M. (P.M.)					
Date	Time		Printed name of provid	ler/agent	Signature of prov	vider/agent	
		A.M. (P.M.)					
Date	Time						
*Patient/Other legally responsible person signature				Relationship (if other than patient)			
*Witness Signature				Printed Name			
□ UMC 60	2 Indiana Avenu	e, Lubbock, TX ´	79415				
□ OTHER	Address:						
Address (Street or P.O. Box)			City, State, Zip Code				
Interpretatio	on/ODI (On Dem	and Interpreting)	□ Yes □ No				
				Date/Time	(if used)		
Alternative	forms of commu	nication used	\Box Yes \Box No				
				Printed nan	ne of interpreter	Date/Time	







Critical Care Units – Commonly Performed Procedures & Related Complications

Patients in intensive and intermediate care units ("critical care units") may have many procedures done to manage their care and to let physicians and nurses know how they are progressing. Some of the most commonly performed procedures, their nature and purpose, substantial risks, potential benefits, and medically reasonable alternatives include:

Arterial Line Insertion

<u>Nature and purpose</u>: A thin plastic tube is placed into an artery. This is usually placed in an artery at the wrist, but may also be placed in an artery in the foot, groin, upper arm, or armpit. This catheter is used to measure blood pressure with each beat of the heart and to draw blood for various studies including measurement of oxygen and carbon dioxide levels to provide information about lung function. This procedure may need to be repeated if the patient remains in the critical care unit for an extended time, or if the line stops functioning or the patient develops a fever.

<u>Substantial risks</u>: Most of the potential complications are related to the risk of bleeding from the artery or the risk of a clot forming in the artery. These include bruising around the site of insertion and blood clot formation around the catheter. A blood clot may reduce blood flow to the arm or leg that has the tube in it. This vascular injury may require surgical correction or very rarely can cause loss of the limb. Pain while placing the catheter may occur, although we provide medication to prevent this. Any catheter in the body has a risk of allowing infection to enter the body.

<u>Benefits</u>: Continuous measurement of blood pressure and evaluation of the response to treatment. Blood draws from this catheter are painless. Most critical care patients require multiple blood tests each day. Blood must be drawn from an artery to determine how well the lungs are working and how they are responding to treatment. Insertion of an arterial line allows us to obtain such blood samples without using a needle each time, thus saving the patient from the pain of repeated needle sticks.

<u>Medically reasonable alternatives</u>: Blood pressure may be obtained by an automatic blood pressure cuff, although this method may not be reliable in patients who are critically ill. Blood may be drawn from an artery or vein each time a sample is required.

Pulmonary Artery Catheter Insertion

<u>Nature and purpose</u>: A long thin plastic tube is placed into a large vein in the neck, below the collarbone, or in the groin. The catheter passes through the right side of the heart and into the artery in the lung. It is commonly used in patients with trauma, severe infection heart failure, renal failure, and other life-threatening conditions. With a pulmonary artery catheter, we can measure the pressure in the heart and blood vessels and the volume of blood the heart is pumping. This tells us how well the heart is functioning and provides information about the patient's fluid balance. The doctor uses this information to decide what medications or treatments would be helpful. This procedure may need to be repeated if the patient remains in a critical care unit for an extended time, or if the patient develops a fever.

<u>Substantial risks</u>: Potential complications are related to the risk of bleeding during the insertion of the catheter and the risk of accidental puncture of an artery, vein or the lung during placement of the catheter. If the lung is punctured, there is a risk of a collapsed lung requiring the insertion of a chest tube to remove the air around the lung. If an artery or vein is punctured severe bleeding can occur, which may require a transfusion, surgical repair, or may rarely cause death. A blood clot can occur around the catheter. Additional risks result from clot formation around the catheter that can result in blockage of the vein or the movement of the clot into the lungs (called a pulmonary embolus). If the tube is passed too far and enters the heart, irregular heart rhythms may occur; these are easily controlled by pulling the catheter back. Damage to the heart valves can also occur. Pain while placing the catheter may occur, although we provide medication to prevent this. Any catheter in the body has a risk of allowing infection to enter the body.

Benefits: This catheter allows accurate and continuous determination of fluid requirements, heart function, and adequacy of oxygen being delivered to vital tissues.

Medically reasonable alternatives: We have no other way to obtain this information continuously or in a timely manner.





<u>Nature and purpose</u>: A long thin plastic tube is placed into a large vein, usually in the neck, below the collar bone or in the groin. This special IV allows us to give nourishment, fluids, and medications to the patient and also to monitor the pressure in the patient's central vein. This procedure may need to be repeated if the patient remains in a critical care unit for an extended time, or if the patient develops a fever.

<u>Substantial risks</u>: Potential complications are related to the risk of bleeding during the insertion of the catheter and the risk of accidental puncture of an artery, vein, or the lung during placement of the catheter. If the lung is punctured, there is a risk of a collapsed lung requiring the insertion of a chest tube to remove the air around the lung. If an artery or vein is punctured severe bleeding can occur, which may require a transfusion or even surgical repair. A blood clot can occur around the catheter. Pain while placing the catheter may occur, although we provide medication to prevent this. Any catheter in the body has a risk of allowing infection to enter the body.

<u>Benefits</u>: This line allows measurement of central venous pressure, which may be helpful to doctors in making decisions regarding treatment. Blood samples can be drawn from this line. The size of this line allows us, when needed, to rapidly give fluids, medications, or blood products. Medications that may irritate smaller veins and cause pain are not as irritating to the larger central vessels, so administration may not be as uncomfortable. In some patients who have poor veins, a central line may be the only way to provide fluids, medications, and blood products.

<u>Medically reasonable alternatives</u>: A peripherally inserted central catheter can also be used to deliver medications, nutrition and fluids to the central circulation.

Peripherally Inserted Central Catheter (PICC):

<u>Nature and purpose</u>: A long thin plastic tube is placed in the arm and threaded into one of the major veins. It is usually placed to give medications that can only be given through veins. This procedure may need to be repeated if the patient remains in a critical care unit for an extended time, or if the patient develops a fever.

<u>Substantial risks</u>: Potential complications are: bleeding, displacement of the tube into the heart or lungs, blood clot formation, and loss of function of the line. Pain while placing the catheter may occur, although we provide medication to prevent this. Any catheter in the body has a risk of allowing infection to enter the body.

Benefits: This central vein IV can be safely maintained for weeks at a time to administer nutrition, medications, and sometimes to draw blood.

<u>Medically reasonable alternatives</u>: A central line can also be used to deliver medications, nutrition and fluids to the central circulation. IVs can be placed in the hands, arms.

Transesophageal Echocardiogram:

<u>Nature and Purpose:</u> Passing of a flexible tube through the mouth into the food pipe and stomach, to bounce sound waves off the heart and image heart. This is used primarily to detect possible blood clot or abnormality of the heart.

Substantial Risks: Risks include pain, severe bleeding, esophageal perforation, aspiration, medication reaction, minor throat irritation, inflammation, infection at IV site.

Benefits: Detection of possible blood clots or abnormality of the heart

Medically Reasonable Alternatives: A transthoracic echocardiogram can also be used to detect abnormalities of the heart and blood clots.

Sedation, Procedural or Maintenance:

<u>Nature and purpose</u>: Sedation refers to the use of medicines to cause sleepiness, reduce anxiety, and to reduce or eliminate pain. Sedation is used both to keep patients comfortable while they are in critical care units and for potentially painful procedures, some of which we have mentioned above. We consider the adequate control of pain and fear one of our primary functions, so we administer these drugs to our patients as a matter of course. When painful procedures are performed, we will often increase the dose or add another drug.





Lubbock, Texas

<u>Substantial risks</u>: Decreased level of awareness, decreased blood pressure, unconsciousness or sleeping for a prolonged period. These medications may also cause the patient to breathe less frequently or deeply, thus necessitating a higher level of oxygen or ventilator support. Additional risks include permanent organ damage, memory dysfunction/memory loss, and potential to convert to general anesthetic if the sedation is not adequate. Certain complications may result from the use of any anesthetic including respiratory problems, drug reaction, paralysis, brain damage or even death. I (we) also realize that the following hazards may occur in connection with this particular procedure related to anesthesia: <u>Allergic reaction to medication, breathing problems, depression, choking on stomach contents (aspiration), cardiac or respiratory arrest, inadequate sedation, need for extended observation in the hospital</u>

<u>Benefits</u>. Usually the agents used will block memory of the patient's time in the critical care unit. Sedation helps patients remain calm and less likely to pull out tubes or drains or lines which would then have to be replaced.

Medically reasonable alternatives: Use of restraints on the hands (mittens), wrists, or ankles or chest and constant observation.

Intubation and Mechanical Ventilation:

<u>Nature and purpose</u>: Intubation means placing a clear plastic breathing tube through the patient's mouth or nose and down into the windpipe. Once placed, the tube is connected to a breathing machine called a mechanical ventilator (respirator). This procedure is commonly done as part of anesthesia for surgery. In intensive care patients, the endotracheal tube may be left in place when the operation is finished. Or it may be inserted when the patient is not able to breathe properly or cannot prevent liquids (saliva or vomit) from passing into the lungs. The endotracheal tube allows passage of oxygen and breathing medications into the lungs, provides a barrier to prevent saliva and vomit from entering the lungs, and provides a way for the critical care team to suction out mucous that blocks the airway. The ventilator uses pressure to deliver oxygen into the lungs.

<u>Substantial risks</u>: During placement of the tube a tooth may be damaged or knocked out. Injury may also occur to the nose, mouth, throat, vocal cords, windpipe, or lungs. If the tube stays in place a long time the vocal cord may be injured. Some patients experience decreased oxygen levels or heart beat irregularities while the tube is being placed. The endotracheal tube may accidentally be placed into the esophagus (swallowing tube) resulting in air in the stomach and deceased oxygen in the lung. A sick or injured lung could collapse and requirement placement of a chest tube. Any tube in the body has a risk of allowing infection to enter the body. All patients receiving mechanical ventilation are constantly monitored to rapidly detect any problems. The patient cannot speak when the endotracheal tube is in place. It is often uncomfortable to have this tube in place so the patients are usually sedated.

<u>Benefits</u>: To breathe for the patient when he/she is unable to, to raise the oxygen levels in the blood, to protect the lungs from saliva and vomit, and to provide a way to remove sputum (mucous) from the lungs.

<u>Medically reasonable alternatives</u>: None. If the decision has been made to place an endotracheal tube, the patient is usually critically ill and has failed to respond to other treatment alternatives such as an oxygen mask.

Bronchoscopy:

<u>Nature and purpose</u>: A tube is placed into the lung so the doctor can see the lining of the lungs, evaluate and clean out the airways. The doctor can also take specimens for culture in the case of a suspected pneumonia or biopsy the lung or bronchial tubes to diagnose the condition causing the respiratory problem. The tube may be passed through the endotracheal tube (see above) or through either the nose or mouth if the patient does not have an endotracheal tube in place. Sedation is given to prevent discomfort and coughing. Oxygen levels are monitored throughout the procedure.

<u>Substantial risks</u>: If the bronchoscopy is done for suctioning to remove secretions, rarely it may cause trauma to the bronchial tubes resulting in minor bleeding. The oxygen level may decrease while the bronchoscope is in place, but we monitor for and treat this. A biopsy may cause bleeding, which is usually minor, but rarely can be severe and life threatening. A lung biopsy may cause the lung to collapse and require placement of a chest tube (see below).

<u>Benefits</u>: Cleaning out secretions may improve oxygen and carbon dioxide levels. Cultures and biopsies may provide important information resulting in changes in treatment.

<u>Medically reasonable alternatives</u>: The doctor can use chest x-rays and sputum specimens from coughing or routine suctioning, but these may be less accurate. Chest physiotherapy (clapping on the chest wall) can help loosen secretions and re-expand the lung. A lung biopsy may be done surgically.





Chest Tube Insertion:

<u>Nature and purpose</u>: A tube is placed into the chest cavity to correct a collapsed lung by removing air, blood, or fluid. To prevent pain upon insertion an anesthetic is used. The tube is inserted through a small incision in the chest wall and is attached to a drainage system.

Substantial risks: Pain while placing the chest tube may occur, although we provide medication to prevent this. Rarely bleeding may occur.

Benefits: The lung will re-expand once air, blood or fluid is removed.

Medically reasonable alternatives: There is no alternative method for removing large amounts of air, blood, or fluid.

Temporary Dialysis Catheter Insertion:

<u>Nature and purpose:</u> A temporary catheter is placed in one of the major veins (groin or neck) for dialysis due to kidney failure, excessive volume in the body, high potassium levels, intoxication.

<u>Substantial risks</u>: Potential complications are related to the risk of bleeding during the insertion of the catheter and the risk of accidental puncture of an artery, vein, or the lung during placement of the catheter. If the lung is punctured, there is a risk of a collapsed lung requiring the insertion of a chest tube to remove the air around the lung. If an artery or vein is punctured severe bleeding can occur, which may require a transfusion or even surgical repair. A blood clot can occur around the catheter. Pain while placing the catheter may occur, although we provide medication to prevent this. Any catheter in the body has a risk of allowing infection to enter the body.

Benefits: Blood filtration

Medically reasonable alternatives: There is no alternative method for blood filtration.

