

Consent for Commonly Performed Procedures in the Adult Critical Care Units

I, the undersigned, understand that the adult 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 adult 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 to 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.

I, _____, consent to the treatments and/or procedures indicated by my initials below, which in
Name of Person Consenting

the judgment of my critical care units’ physicians, may be considered necessary or advisable for
 _____’s diagnosis or treatment, and which may be performed by any of the adult critical
Patient’s Name

care units’ physicians and their associates and assistants (including resident physicians). I understand that this consent will be considered valid for up to 60 contiguous days of admission in the Adult Critical Care Unit. 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.

<u>Procedures</u>	<u>Initials of patient or representative</u>
Arterial Line Insertion	_____
Pulmonary Artery Catheter Placement.....	_____
Central Venous Line Insertion.....	_____
Lumbar Puncture.....	_____

<u>Procedures</u>	<u>Initials of patient or representative</u>
Sedation, Maintenance or Procedural	_____
Bronchoscopy.....	_____
Chest Tube Insertion.....	_____
Thoracentesis	_____

Date Signed: ____/____/____ Expires: ____/____/____

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Patient Name: _____ Patient Identification #: _____

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I understand that physicians who are fellows or residents (resident physicians), may also be involved in the procedure(s), including performing one or more significant task. I further understand that if resident physicians are involved:

- They will perform portions of the procedure(s) based on their level of competence;
- It will be decided at the time of the procedure(s) which resident physicians will participate and their manner of participation, taking into account the following factors: 1) my condition, 2) the availability of resident physicians with the necessary competence, and 3) the knowledge of the adult critical care unit physician of the resident physicians' skill sets;
- Any resident physicians performing significant tasks will be under the supervision of the adult critical care unit physician, though based on the resident physician's level of competence, the adult critical care unit physician may not be physically present in the same room for some or all of the significant tasks performed by resident physicians.

I have had the opportunity to ask any questions that I have regarding resident physician involvement.

I understand that certain significant tasks may be performed by qualified medical practitioners who are not physicians, acting within their scope of practice as permitted by State law and their clinical privileges granted by the hospital.

CONSENT

Patient Signature _____ Date _____ Time _____

Patient Printed Name _____

Staff Witness Signature _____ Staff Witness Printed Name _____

SIGNATURES FOR CONSENT WHEN GIVEN BY REPRESENTATIVE OF PATIENT

If patient is unable to consent, complete the following:

- Patient is a minor, or
- Patient is unable to consent because: _____

Patient's Name _____

Representative's Signature _____ Date _____ Time _____

Representative's Printed Name _____ Relationship to Patient _____

Staff Witness Signature _____ Staff Witness Printed Name _____

SIGNATURE OF PHYSICIAN WHO OBTAINED CONSENT

I certify that the procedure(s) described above, including the substantial risks, benefits, possible complications, anticipated results, alternative treatment options (including non-treatment) and their attendant risks and benefits, the likelihood of success and the possible problems related to recuperation, were explained by me to the patient or his / her legal representative.

Date _____ Time _____

- Consent obtained by telephone.
- Consent obtained with use of interpreter.

Name of interpreter _____

Signature of Physician Who Obtained Consent _____

Physician Identification Number _____



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Patient Name: _____ Patient Identification #: _____

Adult 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:

Nature and purpose: 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.

Substantial risks: 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 plastic 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.

Benefits: 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.

Medically reasonable alternatives: 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:

Nature and purpose: 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.

Substantial risks: 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.

Central Venous Line Insertion:

Nature and purpose: 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. A special central line may be placed to use for dialysis or

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plasmapheresis. 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.

Substantial risks: 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. Often the central line catheters have several openings to permit the infusion of more than one type of fluid or drug. Occasionally, the catheter may move after insertion so that one of the openings is no longer in the vein and fluid or medications may leak out of the catheter and into the tissues or into the space between the lung and chest wall (this is called the pleural space). Any catheter in the body has a risk of allowing infection to enter the body.

Benefits: 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.

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

Sedation, Procedural or Maintenance:

Nature and purpose: 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.

Substantial risks: 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.

Benefits: 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.

Use of Opioid Medications for Sedation:

The risks and benefits of nonopioid alternatives as appropriate to my plan of care, as well as my personal preferences related to the treatment of pain, have been discussed with me.

- I have been informed that alternatives available at this facility may include, but are not limited to, acetaminophen, nonsteroidal anti-inflammatory and other non-narcotic and pain modulating medications, nerve blocks, and hot or cold therapy.
- I have received the Florida Department of Health educational pamphlet containing information about available non-opioid alternatives for the treatment of pain.
- The advantages and disadvantages of the use of nonopioid alternatives, as well as my relative risk of controlled substance abuse or misuse (taking into account my history) have been discussed with me.

Lumbar Puncture (spinal tap):

Nature and purpose: Lumbar puncture refers to a procedure in which a needle is inserted between two lumbar bones (lower back) to remove a sample of cerebrospinal fluid (the fluid that surrounds your brain and spinal cord). A lumbar puncture can help diagnose serious infections, such as meningitis and other disorders of the central nervous system.

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Lumbar Puncture (spinal tap) (continued):

Substantial risks: Skin penetration carries a risk of infection. The chance of infection requiring antibiotic treatment is rare. Bleeding, (epidural hematoma or subarachnoid hemorrhage) following a lumbar puncture. In rare cases, compression or herniation of the brainstem may occur following a lumbar puncture because of increased intracranial pressure and the presence of a brain tumor or other lesion. A CT or MRI performed prior to the procedure helps determine if there is increased intracranial pressure in advance of a lumbar puncture. Spinal cord injury with nerve damage is a rare complication. Headache after the procedure is common.

Benefits: Help diagnose meningitis and other central nervous system disorders, which if unidentified and/or undertreated may lead to permanent neurological damage and/or death. It helps guide appropriate treatment.

Medically reasonable alternatives: None for obtaining spinal fluid. Treat with prolonged (3 weeks) antibiotic therapy with risk of unnecessary prolonged antibiotic administration with prolonged hospitalization.

Bronchoscopy:

Nature and purpose: 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

Substantial risks: 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).

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

Medically reasonable alternatives: 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:

Nature and purpose: A tube is placed into the chest cavity between the lung and chest wall 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.

Thoracentesis:

Nature and purpose: A catheter loaded on a needle is inserted into the chest cavity between the lung and chest wall to obtain a sample to be sent to the lab for testing and to correct a collapsed lung by removing air, blood, or fluid. To prevent pain upon insertion, an anesthetic is used. The catheter is inserted through a small incision in the chest wall and is attached to a drainage system. Fluid/air is suctioned out from the space and catheter is removed at the end of procedure.

Substantial risks: Pain while inserting catheter, although we provide medication to prevent this. Occasionally needle may injure lung/lining of the lung and may lead to air inserted into the space between chest wall and lung leading to collapsed lung. Rarely bleeding may occur.

Benefits: Fluid drawn can help ascertain the reason for accumulation of fluid in the space to administer appropriate therapies. The lung will re-expand once air, blood or fluid is removed improving breathing status.

Medically reasonable alternatives: Other than chest tube mentioned above there is no alternative method for removing fluid/blood.



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