

1. Page 2 is the "consent" form

- a. At the top of the page ask the patient if his/her physician or healthcare provider performing the procedure explained the proposed procedure and the risks involved to his/her satisfaction. Circle yes or no. Have the patient initial their answer. If the patient answers "NO", the nurse stops the process and contacts the physician or healthcare provider.
- b. Line 1- fill in the patient's name and the operating physician's or healthcare provider performing the procedure's full name.
- c. Ask the patient to answer in his own words what the physician or healthcare provider performing the procedure has told him/her, what their condition is and write their answer in the blank (if the patient's response does not match the proposed procedure, notify the physician or healthcare provider performing the procedure).
- d. Line 2- write in the ordered procedure (no abbreviations).
- e. Line 3- have the patient read statements and ask if they understand, no signature is necessary.
- f. Line 4- Ask the patient if they consent to the use of blood and circle their response. Ask the patient to initial their response.
- g. Lines 5&6- have the patient read and acknowledge understanding
- h. Line 6- only needs to be filled in if the physician or healthcare provider performing the procedure has ordered additional risks for the proposed procedure. If none ordered, leave blank.
- i. Line 7- have the patient read and acknowledge understanding.

2. Page 4 Panels

- a. Top box is only for patients having surgery that will require tissue other than his/her own. Leave this box blank if it does not apply.
- b. Box 2 is only to be checked if the proposed procedure does not have a risk panel assigned. Leave blank if the procedure does have a panel.
- c. Box 3 is the risk panel for blood for HMH and should be checked for all patients at HMH and each section should be initialized by the patient.
- 3. Pages 4-14 contain the risk panels for the proposed procedure. Check the corresponding panel to the procedure, ordered by the physician or healthcare provider performing the procedure, and have the patient initial in the appropriate blank.

4. Signing the consent:

- a. After the patient has read the entire consent, fill in the date and time, have the patient sign the consent (the <u>patient</u> must sign as long as he/she is competent. If the patient is not competent, the appropriate legal representative may sign for the patient (System PC/PS23 for the complete list). If a translator is being used, he or she must sign the consent if he or she is physically present. If a video-conference or tele-conference is used, such that he or she is not physically present, it is sufficient to write the translator's name and/or ID number on the consent form in lieu of having the translator sign the consent form.
- b. The individual witnessing the patient's signature must then sign as the witness.
- 5. If the nurse is unable to fill in any of the blanks on this form, the reason for the blank should be explained during the handoff, (i.e. laterality unknown, physician or healthcare provider performing the procedure unknown, patient needs to talk to physician or healthcare provider performing the procedure prior to the procedure.)



HMH2227



Medical Care and Surgical Procedures

Please check or otherwise indicate the name of the hospital where the procedure or other type of medical treatment is to take place.

☐ Houston Methodist Hospital - 6565 Fannin St, Houston, TX 77030
☐ Houston Methodist Baytown Hospital - 4401 Garth Rd, Baytown, TX 77521
\square Houston Methodist Clear Lake Hospital - 18300 Houston Methodist Dr, Houston, TX 77058
☐ Houston Methodist Continuing Care Hospital - 701 S Fry Rd, Katy, TX 77450
☐ Houston Methodist Sugar Land Hospital - 16655 Southwest Fwy, Sugar Land, TX 77479
\square Houston Methodist The Woodlands Hospital - 17201 Interstate 45 S, The Woodlands, TX 77385
☐ Houston Methodist West Hospital - 18500 Katy Fwy, Houston, TX 77094
☐ Houston Methodist Willowbrook Hospital - 18220 Tomball Pkwy, Houston, TX 77070



Page 1 of 14 Form# HM2227 (10/2019) Version 4 OR Council TO THE PATIENT: You have the right to be informed about 1) your condition, 2) the recommended medical care or surgical procedure, and 3) the risks related to this care/procedure. This disclosure is designed to provide you this information, so that you can decide whether to consent to receive this care/procedure. Please ask your physician or healthcare provider performing the procedure any remaining questions you have before signing this form.

Has your physician or healthcare provider performing the procedure informed you about the medical, surgical, or invasive procedure(s) proposed for you, along with the risks, benefits, alternatives and side effects of the procedure involved to your satisfaction? Y / N ______(Pt. Initials)

satisfaction? Y / N(Pt. Initials)				
1.	I, [Patient's Name] voluntarily request my physician/health care provider [name/credentials] and other health care providers, to treat m condition which is			
2.	I, understand that the following care/procedures are planned for me:			
3.	I understand that during my care/procedure(s) my physician/health care provider may discover other conditions which require additional or different care/ procedure(s) than originally planned.			
	I authorize my physicians/health care providers to use their professional judgment to perform the additional or different care/procedure(s) they believe are needed.			
4.	Please initial each one [] YES [] NO I consent to the use of blood and blood products as necessary for my health during the care/procedure(s). [] YES [] NO [] N/A			
	I consent to the use of perioperative cell salvage (my own blood). I understand that the following risks and hazards may occur in connection with the use of blood and blood products:			
	 Serious infection including but not limited to Hepatitis and HIV which can lead to organ damage and permanent impairment. Transfusion related injury resulting in impairment of lungs, heart, liver, kidneys, and immune system. 			
	3. Severe allergic reaction, potentially fatal.			

Methodist*

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I understand that no warranty or guarantee has been made to me as to result or cure.



5. Just as there may be risks and hazards to my health without treatment, there are also risks and hazards related to the care/procedure(s) planned for me. I understand that all care/procedure(s) involve some risks, ranging from minor to severe. These risks include infection, blood clots in the veins, lungs or other organs, hemorrhage (severe bleeding), allergic reactions, poor wound healing, and death. The chances of these occurring may be different for each patient based on the care/procedure(s) and the patient's current health. 6. ADDITIONAL RISKS OR COMMENTS (line through if none) 7. Granting of Consent for this Care/Procedure(s) In signing below, I consent to the care/procedure(s) described below. I acknowledge the following: • I understand this care/procedure(s) does not guarantee a result or a cure to my condition. • I have been given an opportunity to ask questions I may have about: 1. Alternative forms of treatment, 2. Risks of non-treatment. 3. Steps that will occur during my care/procedure(s), and 4. Risks and hazards involved in the care/procedure(s) I believe I have enough information to give this informed consent. • I certify this form has been fully explained to me and the blank spaces have been filled in. I have read this form or had it read to me. Lunderstand the information on this form. If any of those statements are not true for you, please talk to your physician/health care provider before continuing. Patient/Other Legally Authorized Representative (signature required) Print Name: Signature _____ If Legally Authorized Representative, list relationship to Patient: _____ Time: ___ AM/PM (circle one) Witness: Print Name: Signature Name and/or ID number of the qualified interpreter (if applicable):_____ Signature of qualified interpreter: (if applicable)



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BISKS AND HAZARDS

Tissue: I understand that my physician or healthcare provider may use tissue other than my own, and the following are possible risks from the use of that tissue: (1) The transmission of infectious diseases, including bacterial infection. (2) Allergic reaction and other immunological responses, including rejection of the tissue. (3) Other:
PT INITIALS
e following are the risks and hazards associated by the Texas Medical

Disclosure Panel with treatments and procedures

The Texas Medical Disclosure Panel has not established a risk disclosure standard for the proposed procedure(s). My physician or healthcare provider performing the procedure has discussed with me the risks of the procedure(s) such that I am able to give my informed consent.

PT INITIALS

For HMH

■ Blood transfusions:

- (1) fever
- (2) transfusion reaction, which may include kidney failure and or anemia
- (3) heart failure

- (4) hepatitis
- (5) AIDS
- (6) other infections

PT INITIALS

Autologous Donation: I understand that in some instances, it may be possible to donate my own blood for elective medical procedures. Although this diminishes infectious disease transmission, the transfusion still carries with it the risks of adverse physiological reactions and bacterial contamination. In addition, previously donated autologous units may not always be available or adequate for transfusion needs.

Í (have) (have not) made prior arrangements for autologous transfusion.

Designated Donation: I understand, that, in some cases, it is possible to arrange for designated donations (donations from friends or relatives). However, I also understand that designated donations have not been demonstrated to be safer than blood from the volunteer blood supply. In addition, designated units may not always be available or adequate for transfusion needs.

I (have) (have not) made prior arrangements for designated donations.

PT INITIALS

For HMH

☐ Perioperative Blood Salvage:

During surgery shed blood may be salvaged from the surgical field and reinfused as necessary. Blood salvage may help to decrease the use of donated blood, and therefore reduce the risk of transfusion-transmitted diseases such as HIV and Hepatitis. Shed blood may contain contaminants such as bacteria, medications, tumor cells and fluids (ie, amniotic, gastric). Potential risks include increased risk of bleeding, allergic reactions, infection, and air, fat or fragments of blood clots that may travel and block other blood vessels with possible injury to the supplied tissue which, if severe, could be life threatening.

PT INITIALS

1. CARDIOVASCULAR SYSTEM

I. Cardiac Surgical

- □ (A) Coronary artery bypass, valve replacement.
 - Acute myocardial infarction.
 - Hemorrhage.
 - Kidney failure. (3)
 - (4) Stroke.
 - Sudden death.
 - Infection of chest wall/chest cavity.
 - (7) Valve related delayed onset infection.

PT INITIALS

☐ (B) Heart Transplant.

- (1) Infection.
- (2) Rejection.
- (3) Death.

PT INITIALS

Medical Care and Surgical **Procedures**

II. Cardiac Non-Surgical

□ (A) Coronary angioplasty, coronary stent insertion, pacemaker insertion, AICD insertion, and cardioversion.

- (1) All associated risks as listed under paragraph 2 (B) of this subsection.
- (2) Acute myocardial infarction (heart attack).
- (3) Rupture of myocardium (hole in wall of heart).
- (4) Life threating arrhythmias (irregular heartbeat).
- (5) Need for emergency open heart surgery.
- (6) Sudden death.
- (7) Device related delayed onset infection (infection related to the device that happens sometimes after surgery).

PT INITIALS

III. Cardiac Diagnostic

□ (A) Cardiac catheterization.

- (1) All associated risks as listed under paragraph 2 (B) of this subsection.
- (2) Acute myocardial infarction (heart attack).
- (3) Contrast nephropathy (injury to kidney function due to use of contrast material during procedure).
- (4) Heart arrhythmias (irregular heart rhythm), possibly life threatening.
- (5) Need for emergency open heart surgery.

PT INITIALS

□ (B) Electrophysiological studies.

- (1) Cardiac perforation.
- (2) Life threatening arrhythmias.
 (3) Injury to vessel that may require immediate surgical intervention.
- (4) Stress testing Acute myocardial infarction
- (5) Transesophageal echocardiography Esophageal perforation.

PT INITIALS

2. VASCULAR

(A) Open surgical repair of aortic, subclavian, and iliac, artery aneurysms or occlusions, and renal artery bypass.

- (1) Hemorrhage.
- (2) Paraplegia.
- (3) Kidney damage.
- (4) Stroké.
- (5) Acute myocardial infarction.
- (6) Infection of graft.

PT INITIALS

☐ (B) Angiography (inclusive of aortography, arteriography, venography)-Injection of contrast material into the blood vessels

- Injection of contrast material into the blood vessels

 (1) Injury to or occlusion (blocking) of artery which may require immediate surgery or other intervention.

 (2) Hemorrhage (severe bleeding).

 (3) Damage to parts of the body supplied by the artery with resulting loss of use or amputation (Removal of body part).

 (4) Worsening of the condition for which the procedure is being done.

 (5) Stroke and/or seizure (for procedures involving blood vessels supplying the spine, arms, neck, or head).

 (6) Contrast-related, temporary blindness or memory loss (for studies of the blood vessels of the brain).

 (7) Paralysis (inability to move) and inflammation of nerves (for procedures involving blood vessels supplying the spine).

 (8) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure).

 (9) Thrombosis (blood clot forming at or blocking the

- Thrombosis (blood clot forming at or blocking the

PT INITIALS

blood vessel) at the access site or elsewhere □ (C) Angioplasty (intravascular dilatation technique)

- 1) All associated risks listed under paragraph 2 (B) of this subsection.
- (2) Failure of procedure or injury to blood vessel requiring stent (small, permanent tube placed in blood vessel to keep it open) placement or open surgery.

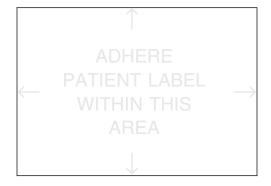
(D) Endovascular stenting (placement of permanent tube into the blood vessel to open it) of any portion of the aorta, iliac or carotid artery or other (peripheral) arteries or veins.

- All associated risks as listed under paragraph 2 (B) of this subsection.
- Change in procedure to open surgical procedure.
 Failure to place stent/endoluminal graft (stent with fabric covering it).
 Stent migration (stent moves from location in which it was placed).

- Vessel occlusion (blocking). Impotence (difficulty with or inability to obtain penile erection) (for abdominal aorta and iliac artery procedure).

PT INITIALS





(E) Vascular thrombolysis (removal or dissolving of blood clots)-percutaneous (mechanical or chemical).

- All associated risks as listed under paragraph 2 (B) of this subsection. Increased risk of bleeding at or away from site of treatment (when using
- medications to dissolve clots).
- (3) For arterial procedures: distal embolus (fragments of blood clot may travel and block other blood vessels with possible injury to the supplied tissue.
- (4) For venous procedures: pulmonary embolus (fragments of blood clot may travel to the blood vessel in the lungs and cause breathing problems or if severe could be life threatening).
- Kidney injury or failure which may be temporary or permanent for procedures using certain mechanical thrombectomy devices).
- (6) Need for emergency surgery.

PT INITIALS

☐ (F) Angiography with occlusion techniques (including embolization and sclerosis) - therapeutic

- (1) For all embolizations
 - (a) Angiography risks (inclusive of aortography, arteriography, venography) injection of contrast material into blood vessels.
 - Unintended injury to or occlusion (blocking) of blood vessels which may require immediate surgery or other intervention.
 - Hemorrhage (severe bleeding).
 - (iii) Damage to parts of the body supplied by the artery with resulting loss of use or amputation (removal of body part).
 - (iv) Worsening of the condition for which the procedure is being done. Contrast nephropathy (kidney damage due to the contrast agent
 - used during the procedure).
 (vi) Unintended thrombosis (blood clot forming at or blocking the
 - blood vessel) at access site or elsewhere.

 (b) Loss or injury to the body part with potential need for surgery, including death of overlying skin for sclerotherapy/treatment of superficial lesions/vessels and nerve injury with associated pain, numbness or tingling or paralysis (inability to move).

 (c) Infection in the form of abscess (infected fluid collection) or septicemia (infection of the blood stream).

 - (d) Nontarget embolization (blocking of blood vessels other than those intended) which can result in injury to tissues
- supplied by those vessels.

 (2) For procedures involving the thoracic aorta and/or vessels supplying the brain, spinal cord, head, neck or arms, these risks in addition to those under section 1 of this subparagraph.
 - (a) Stroke.
 - Seizure.

 - Paralysis (inability to move).
 Inflammation or other injury of nerves.
 For studies of the blood vessels of the brain: contrast-related, temporary blindness or memory loss.
- (3) For female pelvic arterial embolizations including uterine fibroid embolization, these risks in addition to those under section 1 of this subparagraph.
 - (a) Premature menopause with resulting sterility.
 - (b) Injury to or infection involving the uterus which might necessitate hysterectomy (removal of the uterus) with resulting sterility.
 - After fibroid embolization: prolonged vaginal discharge.
 - After fibroid embolization: expulsion/delayed expulsion of fibroid tissue possibly requiring a procedure to deliver/remove the tissue.
- (4) For male pelvic arterial embolizations, in addition to the risks under section 1 of this subparagraph: impotence (difficulty with or inability to obtain a penile erection).
- (5) For embolizations of pulmonary arteriovenous fistulae/malformations, these risks in addition to those under section 1 of this subparagraph.
 - (a) New or worsening pulmonary hypertension (high blood pressure in the lung blood vessels).
 - (b) Paradoxical embolizations (passage of air or an occluding divide beyond the fistula/malformation and the arterial circulation) causing blockage of blood flow to tissue supplied by the receiving artery and damage to tissues served (for example the blood vessels supplying the heart (which could cause chest pain and/or heart attack) or brain (which could cause stroke, paralysis (inability to move) or other neurological injury).
- (6) For varicocele embolization, these risks in addition to those under section 1 of this subparagraph.
 - (a) Phlebitis/inflammation of veins draining the testicles leading to decreased size and possibly decreased function or affected testis and sterility (if both sides performed).
 (b) Nerve injury (thigh numbness or tingling).
- (7) For ovarian vein embolization/pelvic congestion syndrome embolization: general angiography and embolization risks as listed in section 1 of this subparagraph.
- (8) For cases utilizing ethanol (alcohol injection, in addition to the risks under section 1 of this subparagraph; shock or severe lowering of blood
- For varicose vein treatments (with angiography) see subparagraph (L) of this paragraph.

(G)Mesenteric angiography with infusional therapy (Vasopressin) for gastrointestinal bleeding

- All associated risks as listed under paragraph 2 (B) of this subsection.
- Ischemia/infarction of supplied or distant vascular beds (reduction in blood flow causing lack of oxygen with injury or death of tissues supplied by the treated vessel or tissues supplied by blood vessels
- away from the treated site including heart, brain, bowel, extremities).

 Antidiuretic hormone side effects of vasopressin (reduced urine output with disturbance of fluid balance in the body, rarely leading to swelling of the brain). PT INITIALS

☐ (H) Inferior vena caval filter insertion and removal

- All associated risks as listed under paragraph 2 (B) of this subsection.
- Injury to the inferior vena cava (main vein in the abdomen).
- Filter migration or fracture (filter could break and/or move from where it was placed).
- Caval thrombosis (clotting of the main vein in the abdomen and episodes of swelling of legs).
- Risk of recurrent pulmonary embolus (continued risk of blood clots going to blood vessels in the lungs despite filter).
- (6) Inability to remove filter (for "optional"/retrievable filters.

PT INITIALS

(I) Pulmonary angiography

- (1) All associated risks as listed under paragraph 2 (B) of this subsection.
- Cardiac arrhythmia (irregular heart rhythm) or cardiac arrest (heart stops beating).
- Cardiac injury/perforation (heart injury).
 - Death.

PT INITIALS

☐ (J) Percutaneous treatment of pseudoaneurysm (percutaneous thrombin injection versus compression)

- Thrombosis (clotting) of supplying vessel or branches in its
- (2) Allergic reaction to thrombin (agent used for direct injection).

PT INITIALS

(K) Vascular access- nontunneled catheters, tunneled catheters, implanted access

- Pneumorthax (collapsed lung).
 - Injury to blood vessel.
- Hemothorax/hemomediastinum (bleeding into the chest around the lungs or around the heart.
- (4) Air embolism (passage of air into blood vessel and
- possibly to the heart and/or blood vessels entering the lungs).
- (5) Vessel thrombosis (clotting of blood vessel).

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- ☐ (L) Varicose vein treatment (percutaneous via laser, RFA, chemical or other method) without angiography.

 - Deep vein thrombosis (blood clots in deep veins).
 - Hyperpigmentation (darkening of the skin).
 - Skin wound (ulcer)
 - Telangiectatic matting (appearance of tiny blood vessels in treated area).
 - Paresthesia and dysesthesia (numbness or tingling in the area or limb treated).
 - (7) Injury to blood vessel requiring additional procedure to treat.

PT INITIALS

3. DIGESTIVE SYSTEM TREATMENTS AND PROCEDURES.

☐ (A) Cholecystectomy with or without common bile duct exploration.

- Pancreatitis.
- (2) Injury to the tube between the liver and the bowel.
- Retained stones in the tube between the liver (3) and the bowel.
- Narrowing or obstruction of the tube between the liver and the bowel.
- Injury to the bowel and/or intestinal obstruction.

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5. EAR TREATMENTS AND PROCEDURES. ☐ (B) Bariatric Surgery. □ (A) Stapedectomy. (1) Laparoscopic. (1) Diminished or bad taste. (a) Conversion to open procedure. (2) Total or partial loss of hearing in the operated ear. (b) Injury to organs. (3) Brief or long-standing dizziness. (c) Failure of device requiring additional surgical procedure. (4) Eardrum hole requiring more surgery. (d) Obstructive symptoms requiring additional surgical procedure. (e) Development of gallstones (Roux-En-Y). (5) Ringing in the ear. ☐ (B) Reconstruction of auricle of ear for (f) Development of metabolic and vitamin congenital deformity or trauma. (1) Less satisfactory appearance compared to disorders (Roux-En-Y). (g) Suture line leak with abscess or fistula formation. PT INITIALS possible alternative artificial ear. (2) Exposure of implanted material. (2) Open. a. Failure of wound to heal or wound dehiscence □ (C) Tympanoplasty with mastoidectomy. (separation of wound). (1) Facial nerve paralysis.(2) Altered or loss of taste. b. Injury to organs. (2) Altered or loss of faste.(3) Recurrence of original disease process.(4) Total loss of hearing in operated ear. Failure of device requiring additional surgical procedure. d. Obstructive symptoms requiring additional surgical procedure. **Dizziness** Development of gallstones (Roux-En-Y). Development of metabolic and vitamin disorders (Roux-En-Y). (6) Ringing in the ear. PT INITIALS 6. ENDOCRINE SYSTEM TREATMENTS AND PROCEDURES. □ (C) Pancreatectomy (subtotal or total). ☐ (A) Thyroidectomy. Pancreatitis (subtotal). (1) Acute airway obstruction requiring temporary tracheostomy. Diabetes (total). (2) Injury to nerves resulting in hoarseness or impairment of speech. Lifelong requirement of enzyme and digestive medication. Injury to parathyroid glands resulting in low blood (4) Anastamotic leaks. calcium levels that require extensive medication to avoid (D) Total colectomy. serious degenerative conditions, such as cataracts, brittle bones, muscle weakness and muscle irritability. (1) Permanent ileostomy. (2) Injury to organs. (3) Infection. (4) Lifelong requirement of thyroid medication. PT INITIALS (B) Parathyroidectomy. ☐ (E) Subtotal colectomy. (1) Acute airway obstruction requiring temporary tracheostomy. (1) Anastomotic leaks. (2) Injury to nerves resulting in hoarseness or impairment of speech. (2) Temporary colos (3) Infection. (4) Second surgery. (5) Injury to organs. Temporary colostomy. Low blood calcium levels that require extensive medication to avoid serious degenerative conditions, such as cataracts, brittle bones, muscle weakness, PT INITIALS and muscle irritability. ☐ (F) Hepatobiliary drainage/intervention including percutaneous transhepatic cholangiography, percutaneous biliary drainage, percutaneous cholecystostomy, biliary stent placement (temporary (C) Adrenalectomy. (1) Loss of endocrine functions. or permanent), biliary stone removal/therapy (2) Lifelong requirement for hormone replacement therapy (1) Leakage of bile at the skin site or into the abdomen with possible and steroid medication. peritonitis (inflammation of the abdominal lining and pain or if severe (3) Damage to kidneys. can be life threatening. Pancreatitis (inflammation of the pancreas). 7. EYE TREATMENTS AND PROCEDURES. Hemobilia (bleeding into the bile ducts). □ (A) Eye muscle surgery. Cholangitis, cholecystitis, sepsis (Inflammation/infection of the bile (1) Additional treatment and/or surgery. ducts, gallbladder, or blood). Pneumothorax (collapsed lung) or other pleural complications (complications involving the chest cavity). (2) Double vision. (3) Partial or total blindness. (B) Surgery for cataract with or without implantation of intraocular lens. (1) Complications requiring additional treatment and/or surgery. □ (G) Gastrointestinal tract stenting (1) Stent migration (stent moves from location in which it was placed). (2) Esophageal/bowel perforation (creation of a half-order). Esophageal/bowel perforation (creation of a hole or tear in the tube (2) Need for glasses or contact lenses. from the throat to the stomach or in the intestines). (3) Complications requiring the removal of implanted lens. Tumor ingrowth or other obstruction of stent. (4) Partial or total blindness. For stent placement in the esophagus (tube from the throat to the (C) Retinal or vitreous surgery. (1) Complications requiring additional stomach) (a) Tracheal compression (narrowing of windpipe) with resulting or treatment and/or surgery. (2) Recurrence or spread of disease. worsening of shortness of breath. Reflux (stomach contents passing up into the esophagus or higher). (3) Partial or total blindness. Aspiration pneumonia (pneumonia from fluid getting in lungs) (if stent in lower part of the esophagus). (D) Reconstructive and/or plastic surgical procedures of the eye Foreign body sensation (feeling like there is something in the throat) and eve region, such as blepharoplasty, tumor, fracture. (for stent placement in the upper esophagus). lacrimal surgery, foreign body, abscess, or trauma. (1) Blindness. 4. LAPAROSCOPIC/THORACOSCOPIC SURGERY (2) Nerve damage with loss of use and/or feeling to eye or other areas ☐ (A) Laparoscopic/Thoracoscopic risks. The following shall be in addition to of face. risks and hazards of the same surgery when done as an open procedure. Painful or unattractive scarring. (4) Worsening or unsatisfactory appearance. (1) Damage to adjacent structures. (5) Dry eye (2) Abscess and infectious complications. (3) Trocar site complications (e.g., hematoma/bleeding, leakage

- of fluid, or hernia formation).
- (4) Cardiac dysfunction.
- (5) Postoperative pneumothorax.
- (6) Subcutaneous emphysema.
- (7) Conversion of the procedure to an open procedure. PT INITIALS

☐ (B) Use of a power morcellator in laparoscopic surgery.

- (A) If cancer is present, may increase the risk of the spread of cancer.
- (B) Increased risk of damage to adjacent structures.

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☐ (E) Photocoagulation and/or cryotherapy. (F) Repair of vaginal hernia (anterior and/or (1) Complications requiring additional treatment and/or surgery. posterior colporrhaphy and/or enterocele repair). (2) Pain. (1) Uncontrollable leakage of urine. (3) Partial or total blindness. (2) Injury to bladder. ☐ (F) Corneal surgery, such as corneal transplant, (3) Sterility. refractive surgery and pterygium. (4) Injury to the tube (ureter) between (1) Complications requiring additional treatment and/or surgery. the kidney and the bladder. (3) Need for glasses or contact lenses. (4) Partial or total blindness. (5) Injury to the bowel and/or PT INITIALS intestinal obstruction. (6) Mesh erosion (with damage to the vagina and (G) Glaucoma surgery by any method. (1) Complications requiring additional adjacent tissue) PT INITIALS treatment and/or surgery. ☐ (G) Abdominal suspension of the bladder (2) Worsening of the glaucoma. (retropubic urethropexy). (3) Pain. (4) Partial or total blindness. PT INITIALS Uncontrollable leakage of urine. (2) Injury to bladder. ☐ (H) Removal of the eye or its contents (3) Injury to the tube (ureter) (enucleation or evisceration) (1) Complications requiring additional between the kidney and the bladder. treatment and/or surgery.

(2) Worsening or unsatisfactory appearance.

(3) Recurrence or spread of disease. (4) Injury to the bowel and/or intestinal obstruction. PT INITIALS PT INITIALS ☐ (H) Conization of cervix. (I) Surgery for penetrating ocular injury, including intraocular foreign body.
 (1) Complications requiring additional treatment (1) Hemorrhage with possible hysterectomy to control. and/or surgery. Sterility. (2) Possible removal of the eye. (3) Injury to bladder. (3) Pain. PT INITIALS (4) Injury to rectum. (4) Partial or total blindness. PT INITIALS (I) Dilation and curettage of uterus (diagnostic/therapeutic). 8. FEMALE GENITAL SYSTEM TREATMENTS AND PROCEDURES. A) All fallopian tube and ovarian surgery with or without hysterectomy, including removal and lysis of adhesions.
(1) Injury to the bowel and/or bladder.
(2) Sterility.
(3) Failure to obtain fertility (if applicable).
(4) Failure to obtain sterility (if applicable). (1) Hemorrhage with possible hysterectomy. (2) Perforation of the uterus. (3) Sterility. (4) Injury to the bowel and/or bladder. (5) Abdominal incision and operation to correct injury. (5) Loss of ovarian functions or hormone (J) Surgical Abortion/dilatation and curettage/dilatation and production from ovary(ies). PT INITIALS evacuation (a) Removing fibroids (uterine myomectomy).
(b) Uncontrolled leakage of urine. (1) Hemorrhage with possible hysterectomy to control. (2) Perforation of the uterus. Injury to bladder. Sterility. (3) Sterility. Injury to the tube (ureter) between the (4) Injury to the bowel and/or bladder. kidney and the bladder.
Injury to the bowel and/or intestinal obstruction.
May need to convert to hysterectomy.
If a power more celebrate in laparoscopic surgery is (5) Abdominal incision and operation to correct injury. (K) Medical Abortion/non-surgical (1) Hemorrhage with possible need for surgical utilized, include the following risks: If cancer is present, may increase the risk of the intervention. (2) Failure to remove all products of conception. spread of cancer. Sterility. PT INITIALS Increased risk of damage to adjacent structures. PT INITIALS (C) Uterine suspension. (L) Selective salpingography and Fallopian tube recanalization. 1) Uncontrolled leakage of urine. (2) Injury to bladder.
(3) Sterility.
(4) Injury to the tube (ureter) between the kidney and the bladder. (1) Perforation (hole) created in the uterus or Fallopian tube. (2) Ectopic pregnancy (pregnancy outside of the uterus). (3) Pelvic infection. (5) Injury to the bowel and/or intestinal obstruction. PT INITIALS ☐ (M) Fallopian tube occlusion (for sterilization with or without ☐ (D) Removal of the nerves to the uterus hysterectomy) (presacral neurectomy). (1) Perforation (hole) created in the uterus or Fallopian tube. 1) Uncontrolled leakage of urine. (2) Future ectopic pregnancy (pregnancy outside of the uterus) (2) Injury to bladder.
(3) Sterility.
(4) Injury to the tube (ureter) between the kidney and the bladder.
(5) Injury to the bowel and/or intertional particular and/or intertional p (3) Pelvic infection. (4) Failure to obtain sterility ☐ (N) Hysteroscopy intestinal obstruction. (1) Perforation (hole) created in the uterus. (6) Hemorrhage, complications of hemorrhage, with additional operation. (2) Fluid overload/electrolyte imbalance. PT INITIALS (3) Possible hysterectomy. (1) Uncontrollable leakage of urine.
(2) Injury to bladder. (4) Abdominal incision to correct injury. PT INITIALS Sterility.
Injury to the tube (ureter) between the kidney and the bladder.
(5) Injury to the bowel and/or íntestinal obstruction.
(6) Need to convert to abdominal incision.



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9. HEMATIC AND LYMPHATIC SYSTEM.

□ (A) Transfusion of blood and blood components.

- (1) Serious infection including but not limited to Hepatitis and HIV which can lead to organ damage and permanent impairment.
- (2) Transfusion related injury resulting in impairment of lungs, heart, liver, kidneys, and immune system.
- (3) Severe allergic reaction, potentially fatal.

PT INITIALS

☐ (B) Splenectomy.

- (1) Susceptibility to infections and increased severity of infections.
- (2) Increased immunization requirements.

PT INITIALS

10. BREAST SURGERY (NON-COSMETIC)

☐ (A) Radical or modified radical mastectomy.

- (1) Limitation of movement of shoulder and arm.
- (2) Swelling of the arm.
- (3) Loss of the skin of the chest requiring skin graft.
- (4) Recurrence of malignancy, if present.
- (5) Decreased sensation or numbness

of the inner aspect of the arm and chest wall.

PT INITIALS

(B) Simple mastectomy

- (1) Loss of skin of the chest requiring skin graft,
- (2) Recurrence of malignancy, if present.
- (3) Decreased sensation or numbness of the nipple. PT INITIALS

(C) lumpectomy

- (1) Loss of skin of the chest requiring skin graft,
- (2) Recurrence of malignancy, if present.
- (3) Decreased sensation or numbness of the nipple. PT INITIALS

(D) Open biopsy

- (1) Loss of skin of the chest requiring skin graft.
- (2) Recurrence of malignancy, if present.
- (3) Decreased sensation or numbness of the nipple.

PT INITIALS

11. MALE GENITAL SYSTEM.

☐ (A) Orchidopexy [reposition of testis(es)].

- (1) Removal of testicle.
- (2) Atrophy (shriveling) of the testicle with loss of function.

PT INITIALS

(B) Orchiectomy [removal of the testis(es)].

- (1) Decreased sexual desire.
- (2) Difficulties with penile erection.

(3) Permanent sterility (inability to father children if both testes are removed).

(C) Vasectomy.

(1) Loss of testicle.

(2) Failure to produce permanent sterility (inability to father children).

12. MATERNITY AND RELATED CASES.

☐ (A) Delivery (vaginal).

- (1) Injury to bladder and/or rectum including a fistula (hole) between bladder and vagina and/or rectum and vagina.
- (2) Hemorrhage (severe bleeding) possibly requiring blood administration and/or hysterectomy (removal of uterus) and/or artery ligation (tying off) to control.
- (3) Sterility (inability to get pregnant).
- (4) Brain damage, injury or even death occurring to the fetus before or during labor and/or vaginal delivery whether or not cause is known.

PT INITIALS

☐ (B) Delivery (cesarean section).

- (1) Injury to bowel and/or bladder.
- (2) Sterility (inability to get pregnant).
- (3) Injury to ureter (tube between kidney and bladder).
- (4) Brain damage, injury or even death occurring to the fetus before or during labor and/or cesarean delivery whether or not the cause is known.
- (5) Uterine disease or injury requiring hysterectomy (removal of uterus).

☐ (C) Cerclage

- (1) Premature labor.
- (2) Injury to bowel and/or bladder.
- (3) Rupture to membranes and possible infection.

PT INITIALS

13. MUSCULOSKELETAL SYSTEM TREATMENTS AND PROCEDURES

- (A) Arthroplasty of any joints with mechanical device.
 (1) Impaired function, such as stiffness, limp, or change in limb length.
 - (2) Blood vessel or nerve injury.
 - (3) Pain or discomfort
 - (4) Blood clot in blood vessel which can block flow of blood to lungs or limb and/or cause swelling in limbs.
 - (5) Failure of bone to heal.
 - (6) Bone infection.
 - (7) Removal or replacement of any implanted device or material.
 (8) Dislocation or loosening requiring additional surgery.
 (9) If performed on a child age 12 or under, include the following

 - risks: problems with appearance, use, or growth requiring additional surgery

PT INITIALS

□ (B) Arthroscopy of any joint.

- 1) Blood vessel or nerve injury.
- (2) Continued pain.
- Stiffness of joint.
- (4) Blood clot in blood vessel which can block flow of blood to lungs or limbs and/or cause swelling in the limbs.
- (6) If performed on a child age 12 or under, include the following risks: problems with appearance, use, or growth requiring additional surgery

PT INITIALS

□ (C) Open reduction with internal fixation.

- (1) Impaired function, such as stiffness, limp, or change in limb
- (2) Blood vessel or nerve injury.
- (3) Pain or discomfort
- (4) Blood clot in blood vessel which can block flow of blood to lungs or limb and/or cause swelling in limbs.
- Failure of bone to heal.
- (6) Bone infection.
- (7) Removal or replacement of any implanted device or material.
- (8) If performed on a child age 12 or under, include the following risks: problems with appearance, use, or growth requiring additional surgery

- (D) Osteotomy.
 (1) Impaired function, such as stiffness, limp, or change in limb length.
 - (2) Blood vessel or nerve injury.
 - Pain or discomfort.
 - (4) Blood clot in blood vessel which can block flow of blood to lungs or limbs and/or cause swelling in limbs.
 - (5) Failure of bone to heal.
 - (6) Bone infection.
 - (7) Removal or replacement of any implanted device or material.
 - (8) If performed on a child age 12 or under, include the following risks: problems with appearance, use, or growth requiring additional surgery

PT INITIALS

□ (E) Ligamentous reconstruction of joints.

- 1) Failure of reconstruction to work.
- (2) Continual instability of the joint.
- (3) Degenerative arthritis.

- (4) Continued pain.
 (5) Stiffness of joint.
 (6) Blood vessel or nerve injury.
- (7) Impaired function and/or scarring.
- (8) Blood clot in limb or lung.
 (9) If performed on a child age 12 or under, include the following risks: problems with appearance, use, or growth requiring additional surgery

PT INITIALS



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☐ (F) Vertebroplasty/Kyphoplasty (1) Nerve/spinal cord injury. (2) Need for emergency surgery. (3) Embolization of cement (cement used passes into the blood vessels and possibly the way to the blood vessels in the lungs). (4) Fracture of adjacent vertebrae (bones in spine) (5) Leak of cerebrospinal fluid (fluid around the brain and spinal cord). (6) Pneumorthax (collapsed lung). Failure to relieve pain. (8) Rib or vertebral (spine) fracture. ☐ (G) If the following procedures are performed on a child age 12 or under, problems with appearance, use, or growth requiring additional surgery should be disclosed. (1) Arthrotomy (opening of joint). (2) Closed reduction with or without pin or external fixation. (3) Surgical management of open wound. (4) Partial existing or removal of bone. Partial excision or removal of bone. Removal of external fixation device. Traction or casting with or without manipulation for reduction. PT INITIALS ☐ (H) Amputation of limb. Pain and/or phantom sensation in removed limb. Need for further surgery. Infection. Hemorrhage (severe bleeding). Difficulty with prosthesis fitting. PT INITIALS 14. NERVOUS SYSTEM TREATMENTS AND PROCEDURES. ☐ (A) Craniotomy, Craniectomy or Cranioplasty (1) Loss of brain function, such as memory and/or ability to Recurrence, continuation or worsening of the condition that required this operation. Stroke. Blindness, deafness, inability to smell, double vision, coordination loss, seizures, pain, numbness and paralysis. (5) Cerebral spinal fluid leak with potential for meningitis and severe headaches. Meningitis. Brain abscess. Persistent vegetative state. Hydrocephalus (abnormal fluid buildup causing pressure in the brain). Seizures (uncontrolled nerve activity). (11) Need for permanent breathing tube and/or permanent feeding tube. PT INITIALS ☐ (B) Cranial nerve operations. (1) Weakness, numbness, impaired muscle function or paralysis. Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse). Seizures (uncontrolled nerve activity). New or different pain. Stroke (damage to brain resulting in loss of one or more functions). Persistent vegetative state (not able to communicate or interact with others). (7) Loss of senses (blindness, double vision, deafness, smell,

□ (C) Spine operation, including laminectomy, decompression, fusion, internal fixation or procedures for nerve root or spinal cord compression; diagnosis; pain; deformity; mechanical instability; injury; removal of tumor, abscess or hematoma (excluding coccygeal operations). Weakness, pain, numbness or clumsiness. Impaired muscle function or paralysis. Incontinence, impotence or impaired bowel function (loss of bowel/bladder control and/or sexual function). Migration of implants (movement of implanted devices). Failure of implants (breaking of implanted devices). Adjacent level degeneration (breakdown of spine above and/or below the level treated). Cerebrospinal fluid leak with potential for severe headaches. Meningitis (infection of coverings of brain and spinal cord). Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse). (10) Unstable spine (abnormal movement between bones and/or soft tissues of the spine). PT INITIALS ☐ (D) Peripheral nerve operation: nerve grafts decompression. nerve decompression, transposition or tumor removal; neurorrhaphy, neurectomy or neurolysis. (1) Numbness (2) (3) Impaired muscle function. Recurrence, continuation, or worsening of the condition that required the operation. Continued, increased or different pain. (5) Weakness PT INITIALS ☐ (E) Transphenoidal hypophysectomy or other pituitary gland operation. Cerebrospinal fluid leak with potential for severe headaches. Necessity for hormone replacement. Recurrence or continuation of the condition that required this operation. Deformity or perforation of nasal septum (hole in wall between the right and left halves of the nose) Facial nerve injury resulting in disfigurement (loss of nerve function controlling muscles in face). Loss of senses (blindness, double vision, deafness, smell, numbness, taste). Stroke (damage to brain resulting in loss of one or more functions). Persistent vegetative state (not able to communicate or interact with others). (9) Headaches. Cerebrospinal fluid shunting procedure or revision. (1) Shunt obstruction (blockage of shunt/tubing causing it to stop draining adequately). Malposition or migration of shunt/tubing (improper positioning or later movement of shunt/tubing causing it to stop draining adequately). Seizures (uncontrolled nerve activity). Recurrence or continuation of brain dysfunction. Injury to internal organs of the chest or abdomen. Brain injury.

Stroke (damage to brain resulting in loss of one or more functions).

Persistent vegetative state (not able to communicate of interact with others)

Loss of senses (blindness, double vision, deafness, smell, numbness, taste).

Cerebrospinal fluid leak with potential for severe headaches. Meningitis (infection of coverings of brain and spinal cord).

Need for prolonged nursing care.

Need for permanent breathing tube and/or permanent feeding tube.

PT INITIALS

PT INITIALS



numbness, taste)

headaches

feeding tube.

Cerebrospinal fluid leak with potential for severe

Need for prolonged nursing care.

Meningitis (infection of coverings of brain and spinal cord).

Need for permanent breathing tube and/or permanent

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(G) Elevation of depressed skull fracture. (1) Loss of brain function such as memory and/or ability to speak. (2) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse). (3) Loss of senses (blindness, double vision, deafness, smell, numbness, taste). Weakness, paralysis, loss of coordination. (5) Cerebrospinal fluid leak with potential for severe headaches. (6) Meningitis (infection of coverings of brain and spinal cord). Brain abscess Persistent vegetative state (not able to communicate or interact with others). Seizures (uncontrolled nerve activity). Need for permanent breathing tube and/or (10)permanent feeding tube. PT INITIALS 15. RADIOLOGY (A) Splenoportography (needle injection of contrast media into the spleen (1) All associated risks as listed under subsection 2 (B) of this section. (2) Injury to the spleen requiring blood transfusion and/or removal of the spleen. PT INITIALS ☐ (B) Chemoembolization (1) All associated risks as listed under subsection 2 (B) of this section. (2) Tumor lysis syndrome (rapid death of tumor cells releasing their contents which can be harmful). (3) Injury to or failure of liver (or other organ in which tumor is located). (4) Risk of the chemotherapeutic agent(s) utilized. (5) Cholecystitis (inflammation of the gall bladder) (for liver or other upper GI embolizations). (6) Abscess (infected fluid collection) in the liver or other embolized organ requiring further intervention. (7) Biloma (collection of bile in or near the liver requiring drainage) (for liver embolizations). PT INITIALS ☐ (C) Radioembolization (1) All associated risks as listed under subsection 2 (B) of this section. (2) Tumor lysis syndrome (rapid death of tumor cells releasing their contents which can be harmful). (3) Injury to or failure of liver (or other organ in which tumor is located). (4) Radiation complications: pneumonitis (inflammation of lung) which is potentially fatal; inflammation of stomach, intestines, gallbladder, pancreas, stomach or intestinal ulcer; scarring of liver. PT INITIALS (D) Thermal and other ablative techniques for treatment of tumors (for curative intent or palliation) including radiofrequency ablation, cryoablatlon, and high intensity focused ultrasound (HIFU) (1) Injury to tumor-containing organ or adjacent organ/structures. Injury to nearby nerves potentially resulting in temporary or chronic (continuing) pain and/or loss of use and/or feeling. (3) Failure to completely treat tumor. PT INITIALS ☐ (E) TIPS (Transjugular Intrahepetic Portosystemic Shunt) and its variants such as DIPS (Direct Intrahepatic Portocaval Shunt) (1) All associated risks as listed under subsection 2 (B)-(D) of this section. (2) Hepatic encephalopathy (confusion/decreased ability to think). (3) Liver failure or injury. (4) Gallbladder injury. (5) Hemorrhage (severe bleeding). (6) Recurrent ascities (fluid building up in abdomen) and/or bleeding. (7) Kidney failure. (8) Heart failure. (9) Death. PT INITIALS ☐ (F) Myelography (1) Chronic continuing pain. (2) Nerve injury with loss of use and/or feeling.

- (G) Percutaneous abscess/fluid collection drainage (percutaneous abscess/seroma/lymphocele drainage and/or sclerosis (inclusive of percutaneous, transguteal, transrectal and transvaginal routes)
 - (1) Sepsis (infection in the blood stream), possibly resulting in shock (severe decrease in blood pressure).
 - (2) Injury to nearby organs.
 - (3) Hemorrhage (severe bleeding).
 - (4) Infection of collection which was not previously infected, or additional infection of abscess.

PT INITIALS

☐ (H) Procedures utilizing prolonged Fluoroscopy

- (1) Skin injury (such as epilation (hair loss), burns or ulcers).
- (2) Cataracts (for procedures in the region of the head).

PT INITIALS

16. RESPIRATORY SYSTEM TREATMENTS AND PROCEDURES

- □ (A) Biopsy and/or excision of lesion of larynx, vocal cords, trachea
 - (1) Loss or change of voice.
 - (2) Swallowing or breathing difficulties.
 - (3) Perforation (hole) or fistula (connection) in esophagus (tube from throat to stomach).

PT INITIALS

- (B) Rhinoplasty or nasal reconstruction with or without septoplasty
 - (1) Deformity of skin, bone or cartilage.
 - (2) Creation of new problems, such as perforation of the nasal septum (hole in wall between the right and left halves of the nose) or breathing difficulty.

PT INITIALS

- ☐ (C) Submucous resection of nasal septum or nasal septoplasty
 - (1) Persistence, recurrence or worsening of the obstruction.
 - (2) Perforation of nasal septum (hole in wall between the right and left halves of the nose) with dryness or crusting.
 - (3) External deformity of the nose.

PT INITIALS

- □ (D) Lung Biopsy
 - (1) Pneumothorax (collapsed lung).
 - (2) Hemothorax (blood in the chest around the lungs).

PT INITIALS

- ☐ (E) Segmental resection of the lung
 - (1) Hemothorax (blood in the chest around the lung).
 - (2) Abscess (infected fluid collection) in the chest.
 - (3) Insertion of tube into space between lung and chest wall or repeat surgery.

PT INITIALS

- ☐ (F) Thoracotomy
 - (1) Hemothorax (blood in the chest around the lung).
 - (2) Abscess (infected fluid collection) in chest.
 - (3) Pneumothorax (collapsed lung).
 - (4) Need for additional surgery.

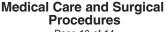
PT INITIALS

- ☐ (G) Thoracotomy with drainage
 - (1) Hemothorax (blood in the chest around the lung).
 - (2) Abscess (infected fluid collection) in the chest.
 - (3) Pneumothorax (collapsed lung).
 - (4) Need for additional surgery.

PT INITIALS

- (3) Transient (temporary) headache, nausea, and/or vomiting.
- (4) Numbness.
- (5) Seizures.

PT INITIALS



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☐ (H) Open tracheostomy Ureterectomy (partial/complete removal of ureter (tube (1) Loss of voice. between kidney and bladder)). (2) Breathing difficulties. (1) Leakage of urine at the surgical site. (3) Pneumothorax (collapsed lung). (2) incomplete removal of stone. (4) Hemothorax (blood in the chest around the lung). (3) Blockage of urine. (5) Scarring in the trachea (windpipe). (4) Damage to organs next to the ureter. (6) Fistula (connection) between trachea into esophagus ☐ (J) Ureterolysis (partial/complete removal of ureter (tube (tube from the throat to stomach) or great vessels. PT INITIALS between kidney and bladder from adjacent tissue)). ☐ (I) Respiratory tract/tracheobronchial balloon dilatation/stenting (1) Leakage of urine at the surgical site. (1) Stent migration (stent moves from position in which it (2) Blockage of urine. was placed). (3) Damage to organs next to ureter. (2) Pneumomediastinum (air enters the space around the (4) Damage or loss of ureter. PT INITIALS airways including the space around the heart). ☐ (K) Ureteral reimplantation (reinserting ureter (tube (3) Mucosal injury (injury to lining of airways). PT INITIALS between the kidney and bladder) into the bladder) 17. URINARY SYSTEM (1) Leakage of urine at surgical site. ☐ (A) Partial nephrectomy (removal of part of the kidney) (2) Blockage of urine. (1) Incomplete removal of stone(s) or tumor, if present. (3) Damage to organs next to the ureter. (2) Blockage of urine. (4) Damage to or loss of the ureter. (5) Backward flow of urine from bladder into ureter. PT INITIALS (3) Leakage of urine at the surgical site. (4) Injury or loss of kidney. (L) Prostatectomy (partial or total removal of prostate) PT INITIALS (5) Damage to organs next to kidney (1) Leakage of urine at surgical site. (2) Blockage of urine. ☐ (B) Radical nephrectomy (removal of kidney and adrenal gland (3) Incontinence (difficulty with control of urine flow). for cancer) (1) Loss of the adrenal gland (gland on top of kidney that (4) Semen passing backward into bladder. (5) Difficulty with penile erection (possible with partial and makes certain hormones/chemicals body needs). probable with total prostatectomy). (2) Incomplete removal of tumor. PT INITIALS (3) Damage to organs next to kidney. PT INITIALS ☐ (M) Total Cystectomy (removal of the bladder) ☐ (C) Nephrectomy (removal of kidney) (1) Probable loss of penile erection and ejaculation in the male. (1) Incomplete removal of tumor if present. Damage to organs next to bladder. (2) Damage to organs next to kidney. (3) This procedure will require an alternate method of (3) Injury to or loss of kidney. PT INITIALS urinary drainage. ☐ (D) Nephrolithotomy and Pyelolithotomy (removal of kidney ☐ (N) Radical cystectomy stone(s)). (1) Probable loss of penile erection and ejaculation in the male.(2) Damage to organs next to bladder. (1) Incomplete removal of stone(s). (2) Blockage of urine. (3) This procedure will require an alternate method of (3) Leakage of urine at surgical site. urinary drainage. Chronic (continuing) swelling of thighs, legs and feet (4) Injury or loss of kidney. (5) Recurrence or spread of cancer if present. PT INITIALS (5) Damage to organs next to the kidney. PT INITIALS ☐ (E) Pyeloureteroplasty (pyeloplasty or reconstruction of the ☐ (O) Partial cystectomy (partial removal of bladder) kidney drainage system) (1) Leakage of urine at surgical site. (1) Blockage of urine. Incontinence (difficulty with control of urine flow). (2) Leakage of urine at surgical site. Backward flow of urine from bladder into ureter (tube between kidney and bladder). (3) Injury to or loss of kidney. Blockage of urine. (4) Damage to organs next to the kidney. PT INITIALS (5) Damage to organs next to bladder. ☐ (F) Exploration of kidney or perinepphric mass PT INITIALS (1) Incomplete removal of stone(s) or tumor, if present. ☐ (P) Urinary diversion (ileal conduit, colon conduit) Blood chemistry abnormalities requiring medication. Development of stones, strictures or infection in the (2) Leakage of urine at surgical site. (3) Injury to or loss of kidney. kidneys ureter or bowel (intestines). (4) Damage to organs next to the kidney. PT INITIALS Leakage of urine at the surgical site. ☐ (G) Ureteroplasty (reconstruction of ureter (tube between This procedure will require an alternate method kidney and bladder)). of urinary drainage. PT INITIALS (1) Leakage of urine at surgical site. (2) Incomplete removal of the stone(s) or tumor (when applicable). (3) Blockage of urine. (4) Damage to organs next to ureter. (5) Damage to or loss of the ureter. PT INITIALS ☐ (H) Ureterolithotomy (surgical removal of stone(s) from the ureter (tube between the kidney and bladder)). (1) Leakage of urine at the surgical site. (2) Incomplete removal of stone. (3) Blockage of urine. (4) Damage to organs next to the ureter. (5) Damage to or loss of the ureter. PT INITIALS



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PATIENT LABEL

WITHIN THIS

AREA

☐ (Q) Ureterosigmoidostomy (placement of kidney drainage tubes into the large bowel (intestine) (1) Blood chemistry abnormalities requiring medication. (2) development of stones, strictures or infection in the kidneys ureter or bowel (intestines). (3) Leakage of urine at the surgical site. (4) Difficulty holding urine in the rectum. PT INITIALS ☐ (R) Urethroplasty (construction/reconstruction of drainage tube from bladder) (1) Leakage of urine at surgical site. Stricture formation (narrowing of urethra (tube from bladder to outside)). (3) Need for additional surgery. PT INITIALS □ (S) Percutaneous nephrostomy/stenting/stone removal Pneumothorax or other pleural complication (collapsed lung or filling of chest cavity on the same side with fluid). Septic shock/bacteremia (infection of the blood stream with possible shock/severe lowering of blood pressure) when pyonephrosis (infected urine in the kidney) present. (3) Bowel (intestinal) injury. (4) Blood vessel injury with or without significant bleeding ☐ (T) Dialysis (technique to replace function of the kidney and clean blood of toxins) (1) Hemodialysis (a) Hypotension (low blood pressure). (b) Hypertension (High blood pressure). (c) Air embolism (air bubble in blood vessel) resulting in

possible death or paralysis.

(d) Cardiac arrhythmias (irregular heart rhythms).

(e) Infection of blood stream, access site, or blood borne (for example; Hepatitis B,C or HIV).

(f) Hemorrhage (severe bleeding as a result of clotting problems or due to disconnection of the blood line.

(g) Nausea, vomiting, cramps, headache and mild confusion during and/or temporarily after dialysis.

(h) Allergic reaction.

(i) Chemical imbalances and metabolic disorders (unintended change in blood minerals).

Pyrogenic reactions (fever).

(k) Hemolysis (rupture of red blood cells).

Graft/fistula damage including bleeding, aneurysm formation (ballooning of vessels), clotting (closure) of graft/fistula.

(2) Peritoneal dialysis

(a) Infection, including peritonitis (inflammation or irritation of the tissue lining of the inside wall of abdomen and

covering organs).
(b) Development of hernias of umbilicus (weakening of abdominal wall or muscle).

(c) Hypertension (high blood pressure).
(d) Hypotension (low blood pressure).

(e) Hydrothorax (fluid in chest cavity).

(f) Arrhythmia (irregular heart rhythm).

(g) Perforation of the bowel.

(h) Sclerosis or scarring of the peritoneum.(i) Weight gain leading to obesity.

Abdominal discomfort/distension.

(k) Heart burn or reflux.

Increase in need for anti-diabetic medication.

(m) Muscle weakness.

(n) Dehydration (extreme loss of body fluid).

(o) Chemical imbalances and metabolic disorders, unintended change in blood minerals).

Allergic reactions.

Nausea, vomiting, cramps, headache, and mild confusion during and/or temporarily after dialysis.

PT INITIALS

18. PAIN MANAGEMENT PROCEDURES

☐ (A) Neuroaxial procedures (injections into or around spine)

(1) Failure to reduce pain or worsening of pain.
(2) Nerve damage including paralysis (inability to move).
(3) Epidural hematoma (bleeding in or around the spine).
(4) Infection.
(5) Seizure.

Persistent leak of spinal fluid which may require surgery.

(6) Persistent leak of spinal fluid which may re (7) Breathing and/or heart problems including cardiac arrest (heart stops beating). (8) Loss of vision.

(9) Stroke.

PT INITIALS

(B) Peripheral and visceral nerve blocks and/or ablations

(1) Failure to reduce pain or worsening of pain. (2) Bleeding.

(3) Nerve damage including paralysis (inability to move).
(4) Infection.

(5) Damage to nearby organ or structure.(6) Seizure.

PT INITIALS

(C) Implantation of pain control devices

(1) Failure to reduce pain or worsening of pain.(2) Nerve damage including paralysis (inability to move).

Epidural hematoma (bleeding in or around the spine).

(4) Infection. (5) Persistent leak of spinal fluid which may require surgery.

PT INITIALS

19. DENTAL SURGERY PROCEDURES

(A) Extraction (removing teeth).
(B) Dry socket (inflammation in the socket of a tooth).

(iii) Permanent or temporary numbness or altered sensation.
(iii) Sinus communication (opening from tooth socket into the sinus cavity)

(iv) Fracture of alveolus and/or mandible (upper and/or lower jaw).

(B) Surgical exposure of tooth in order to facilitate orthodontics.

Injury to tooth or to adjacent teeth and structures.

Failure to get proper attachment to tooth requiring additional procedure.

(2) Endodontics (deals with diseases of the dental pulp).

(A) Apicoectomy (surgical removal of root tip or end of the tooth, with or without sealing it).

Shrinkage of the gums and crown margin exposure.
Sinus communication (opening from tooth socket into the

sinus cavity). (iii) Displacement of teeth or foreign bodies into nearby

(iii) Displacement of teem of loreign bodies into hearby tissues, spaces, and cavities.

(B) Root amputation (surgical removal of portion of one root of a multi-rooted tooth).

(i) Shrinkage of the gums and crown margin exposure.

(ii) Sinus communication (opening from tooth socket into the sinus cavity).

(iii) Displacement of teeth or foreign bodies into nearby tissues, spaces, and cavities.

(C) Root canal therapy (from an occlusal access in order to

clean and fill the canal system).

(i) Instrument separation (tiny files which break within the tooth canal system).

(ii) Fenestration (penetration of walls of tooth into adjacent tissue).

(iii) Failure to find and/or adequately fill all canals.

(iv) Expression of irrigants or filling material past the apex of the tooth (chemicals used to clean or materials used to fill a root may go out the end of the root and cause pain or swelling).

(v) Damage to adjacent tissues from irrigants or

(vi) Fracture or loss of tooth.

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(A) Gingivectomy and gingivoplasty (involves the removal of soft tissue). (i) Tooth sensitivity to hot, cold, sweet, or acid foods.(ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some (B) Anatomical crown exposure (removal of enlarged gingival tissue and supporting bone to provide an anatomically correct gingival relationship). (i) Tooth sensitivity to hot, cold, sweet, or acid foods. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some (C) Gingival flap procedure, including root planing (soft tissue flap is laid back or removed to allow debridement (cleaning) of the root surface and the removal of granulation tissue (unhealthy soft tissue)). Permanent or temporary numbness or altered sensation. Tooth sensitivity to hot, cold, sweet, or acid foods. (iii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some (D) Apically positioned flap (used to preserve keratinized gingival (attached gum tissue) in conjunction with osseous resection (removal) and second stage implant procedure). Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. (E) Clinical crown lengthening (removal of gum tissue and/or bone from around tooth). Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some (F) Osseous surgery-including flap entry and closure (modification of the bony support of the teeth). Permanent or temporary numbness or altered sensation. Tooth sensitivity to hot, cold, sweet, or acid foods. (iii) Loss of tooth. (iv) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. (G)Guided tissue regeneration-resorbable barrier. (i) Permanent or temporary numbness or altered sensation. (ii) Accidental aspiration (into the lungs) of foreign matter. (iii) Rejection of donor materials. (H) Guided tissue regeneration-nonresorbable barrier (includes membrane removal). Permanent or témporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some (iii) Accidental aspiration (into the lungs) of foreign matter. (iv) Rejection of donor materials. (I) Pédicle soft tissue graft procedure. Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some (iii) Rejection of donor materials. (J) Free soft tissue graft protection-including donor site Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some (iii) Rejection of graft. (K) Sub epithelial connective tissue graft procedures. Permanent or temporary numbness or altered sensation. (iii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. (iii) Rejection of graft. (L) Distal or proximal wedge procedure (taking off gum tissue from the very back of the last tooth or between teeth). Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. (M)Soft tissue allograft and connective tissue double pedicle graft from below (creates or augments gum tissue). Permanent or temporary numbness or altered sensation. Tooth sensitivity to hot, cold, sweet, or acid foods. (iii) Shrinkage of the gums upon healing resulting in teeth

appearing longer and greater spaces between

(4)	Implant procedures. (A) Bone grafting (replacing missing bone). (i) Permanent or temporary numbness or altered so (ii) Rejection of bone particles or graft from donor or recipient sites. (iii) Damage to adjacent teeth or bone. (B) Surgical placement of implant body. (i) Blood vessel or nerve injury. (ii) Damage to adjacent teeth or bone fracture. (iii) Sinus communication (opening from tooth sockers sinus cavity). (iv) Failure of implant requiring corrective surgery. (v) Cyst formation, bone loss, or gum disease around the implant.	or		
	ASTIC SURGERY AND SURGERY OF THE INTEGUME STEM.	NTARY		
<u> </u>	Augmentation mammoplasty (breast enlargement wimplant). (A) Bleeding around implant. (B) Sensory changes or loss of nipple sensitivity. (C) Failure, deflation, or leaking of implant requiring replacement. (D) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape). (E) Problems with or the inability to breastfeed.			
(F) Capsular contracture (hardening of breast).				
(2)	Bilateral breast reduction. (A) Skin flap or fat necrosis (injury or death of skin and (B) Loss of nipple or areola. (C) Sensory changes or loss of nipple sensitivity. (D) Problems with or the inability to breastfeed. (E) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape or not desired size).	fat).		
(3)	Rhinoplasty or nasal reconstruction with or without	t		
	septoplasty (repairing the middle wall of the nose). (A) Development of new problems, such as perforation nasal septum (hole in wall between the right and let halves of the nose) or breathing difficulty. (B) Spinal fluid leak. (C) Worsening or unsatisfactory appearance.			
(4)	Reconstruction and/or plastic surgery operations o			
(4)	face and neck. (A) Impairment of regional organs, such as eye or lip function. (B) Recurrence of the original condition. (C) Worsening or unsatisfactory appearance.	PT INITIALS		
(5)	Liposuction (removal of fat by suction). (A) Shock. (B) Pulmonary fat embolism (fat escaping with possible damage to vital organs). (C) Damage to skin with possible skin loss. (D) Loose skin. (E) Worsening or unsatisfactory appearance.	PT INITIALS		

(6) Breast reconstruction with other flaps and/or implants.

(A) Bleeding around implant.

B) Sensory changes or loss of nipple sensitivity

(C) Failure, deflation, or leaking of implant requiring replacement.

(D) Damage to internal organs.

(E) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape).

PT INITIALS



some teeth.

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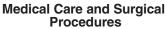
PT INITIALS

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[(7)	Nipple Areolar Reconstruction. (A) Loss of graft. (B) Unsatisfactory appearance.	PT INITIALS
[(8)	Panniculecotomy (removal of skin and fat). (A) Persistent swelling in the legs. (B) Nerve damage. (C) Worsening or unsatisfactory appearance.	PT INITIALS
[<u> </u>	(9)	Tendonitis, tendon release, and trigger releases. (A) Recurrence of symptoms. (B) Damage to blood vessels, nerves, tendons, or muscles. (C) Worsening function.	PT INITIALS
[(10)	Breast reconstruction with flaps. (A) Damage to blood vessels, nerves, or muscles. (B) Loss of flap possibly requiring additional surgery. (C) Damage to internal organs. (D) Increased risk of abdominal wall complications with pregnancy. (E) Abdominal hernias with abdominal flaps. (F) Chronic abdominal pain with abdominal flaps. (G) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape).	PT INITIALS
		(11)	Flap or graft surgery. (A) Damage to blood vessels, nerves, or muscles. (B) Deep vein thrombosis (blood clot in legs or arms). (C) Loss of flap possibly requiring additional surgery. (D) Worsening or unsatisfactory appearance.	PT INITIALS
[٦	(12)	Tendons, nerves, or blood vessel repair. (A) Damage to nerves. (B) Deep vein thrombosis (blood clot in legs or arms). (C) Rupture of repair. (D) Worsening of function.	PT INITIALS





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Research Sometimes tissue, blood, body fluids or cells are removed from your body during surgery. For simplicity we are calling all these things "tissue". Any removed tissue is used for your care, diagnosis and treatment first. After all tests are done, tissue may be left over. You may choose to donate it for medical research. No more tissue will be removed than would normally be removed for your care.



TMH469

Before you decide to donate your tissue, read this information and talk to your doctor or nurse and make sure all your questions are answered.

- You do not have to donate.
- Your choice to donate or not will not affect your healthcare in any way.
- If you change your mind after donating, we will discard any unused tissue.

What is the purpose of donating this tissue?

- Human tissue research can help find new or better ways to diagnose, treat, cure and prevent disease.
- Human tissue research may develop new commercial medical products.

What will happen if you donate this tissue?

- The tissue will be stored in a 'tissue bank' or repository for future use.
- Researchers may use donated tissue by submitting a research plan to either:
 - The Biorepository Resource Allocation Committee (BioRAC) for de-identified tissue (with no information given to the researchers that may personally identify the tissue), or
 - A committee called the Institutional Review Board (IRB). Requests are made to the IRB if the researchers plan to use patients' health information in addition to the tissue.
 In this case, the research plan will describe how the researchers will keep released information private.
- The BioRAC or IRB must approve the research plan before any tissue is released.
- The researchers will be primarily at Houston Methodist but the tissue or information from research on it may be shared with researchers from other universities and private companies.
- At Houston Methodist, your tissue will only be used for research and will not be sold.

Will this tissue be used for genetic research?

This tissue could be used for genetic research or the study of genes. A gene is made from a long chain of molecules in cells called DNA. The molecules are arranged in pairs. The order of the pairs is called "DNA sequencing". Every person has a unique combination of molecule pairs so it is called a genetic code. Researchers are trying to find out if certain codes are linked to diseases.

- Researchers may release the genetic code information to public databases on the Worldwide Web.
- Only genetic code information will be released. Your name or personal information that could identify you will not be released.
- Researchers and others can search these databases for codes that may be linked to certain diseases.
- There is a very small chance that the genetic code could be traced to you. This is only possible if another specimen or information that was already linked to you could be compared to all the information in the database.





What are the possible benefits to you or to others?

There will be no direct medical or personal benefit to you as a result of donating the tissue. The research may benefit other people in the future.

What are the risks?

- There are no medical risks to you.
- Genetic studies may have results that are unique and individual to you and there is a small possibility that it could still be linked to you in the future even though personal information is removed from the sample. A new law prevents employers and health insurers from using genetic information to make hiring or insurance decisions.
- Your tissue could be used in research you would find personally objectionable. It is
 impossible to predict what kinds of research could be performed in the future. Some
 research may be controversial or sensitive and you will not be able to select in which
 research your tissue might be used. When you agree to donate tissue, you agree to allow
 Houston Methodist, its researchers and collaborators to use the tissue in any research
 that the hospital IRB committee approves.

Are there any financial considerations?

- There will be no cost to you if you decide to donate tissue.
- You will not be paid for your tissue.
- If a commercial product is developed from a research project that used your sample, the commercial product will be owned by the sponsor and you will not receive any money or rights to the product.

How will your privacy and the confidentiality be protected?

Houston Methodist Tissue Bank personnel will take careful steps to prevent private information that could identify you from being released.

- Personal information will be taken off any record associated with your tissue before it is studied.
- A code number will be assigned to the tissue.
- Researchers may publish or present their research results in scientific journals or at scientific meetings but will not include any information that will let others know who you are.

How long will you participate and will you be contacted?

If you agree to donate your tissue, it will be saved after the testing for your care is completed. You will not need to do anything and no further participation is required. However, there might be situations when additional information is needed. If you agree to be contacted, the tissue bank may give your contact information to committee-approved researchers.



Donating Tissue for Medical Research

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AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

By signing below, you consent to the use of your excess tissue/blood/body fluid/cell samples and authorize the use and disclosure of your personal health information for research as described in the previous pages.

I have voluntarily agreed to donate my tissue, blood, bodily fluids or cells ("tissue") to Houston Methodist to be used for medical research. I understand that Houston Methodist will not condition treatment, payment, or enrollment or eligibility for benefits (as applicable) on whether I agree to this authorization. As part of this donation, I understand and agree that Houston Methodist may use my personal health information in conducting medical research on my tissue. It may also release my personal health information to other researchers or institutions, or to government agencies, as part of Houston Methodist's research. Finally, I understand that Houston Methodist may release my personal information to other researchers or institutions who may wish to conduct their own research on my tissue.

This authorization is valid until all research activities directly or indirectly related to the tissue bank program of Houston Methodist are terminated, or until I revoke it. I understand that I may revoke this authorization at any time and any identifiable tissue that has not been released from the tissue bank will be destroyed. I understand that the revocation will not apply to information that already has been released or actions that have already been taken in response to this authorization. I understand that if I revoke this authorization, I must do so by contacting Dr. Blythe Gorman, or her designee in Houston Methodist Department of Pathology at 713-441-6409 or write to the Pathology Department MS 205, 6565 Fannin, Houston, TX 77030. I have a right to request a copy of any of my health information that is released under this authorization.

I understand that other researchers or institutions to which Houston Methodist may release my health information may not be covered by Federal or Texas privacy laws. As such, my information may not be protected under these laws once it is disclosed and, therefore, may be subject to re-disclosure or use by such individuals or institutions.

I will be a given a copy of this form to keep.

INITIAL HERE if you agree to be contacted by researchers if additional is needed.					
Signature of Subject or Legally Authorized Representative	 Date				



Donating Tissue for Medical Research

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