RESET SAVE

UMASS MEMORIAL MEDICAL CENTER

TREATMENT AND PROCEDURE CONSENT FORM

NAME:

ADDRESS:

BIRTHDATE/AGE: SEX:

MEDICAL RECORD NUMBER:

PRINT CLEARLY IN INK OR IMPRINT WITH PATIENT'S CARD

1

Treatment or Procedure **(1)**: _____

_____

Additional Space for item 1

Date Procedure will be performed:_____

Attending Physician Directing Treatment Plan or Procedure **(2)**: _____

Provider Performing the Procedure (if different from Attending Physician): _____

Signature of Provider Performing the Procedure: _____

I have explained to the patient/the patient's authorized representative **(3)**:

1. his/her condition
2. the proposed treatment or procedure and its indications
3. the expected results, my inability always to predict results with certainty, and the possibility of an unexpected complication
4. the anticipated benefits and material risks of the treatment/procedure
5. the possible alternatives, including no treatment/procedure
6. if applicable, that photographs or videotapes may be taken for medical/educational purposes (and every attempt will be made to respect patient confidentiality).
7. if applicable, that UMMMC staff members may use and/or discard whatever materials or tissues are removed from his/her body during this procedure. If they are used for research or educational purposes, the patient's anonymity will be maintained. (See Policy on Disposition of Fetal Remains for instructions regarding products of conception)

Information Provided and Discussed: (4)
If applicable, reference or attach informational materials that document risks, benefits and alternatives. Document any deviation from the standard or recommended procedure protocol, modification of the terms of informed consent printed in this form and patient's comments or restrictions, if any.

_____

_____

_____

Additional Space for item 4

(5)_____ **(6)** _____
Date/time of Signature — Signature of Health Care Provider Providing Information to Patient

I understand and acknowledge that the UMass Memorial Medical Center is an educational institution and that medical and other students may participate in procedures as part of their education unless I refuse to permit their participation. I understand that resident physicians may participate in my care under the general supervision of the responsible provider. I also understand that providers such as Residents, Nurse Practitioners and Physician Assistants may perform procedures (and perform significant tasks related to surgery) in accordance with their level of competence, approved scopes of practice and their delineation of privileges. I consent and authorize UMMMC to own, retain, preserve, analyze or dispose of any excess tissues, specimens, or parts of organs that are removed from my body during the procedures described above as long as they are not necessary for my diagnosis or treatment. UMMMC may use or retransfer these items to any entity for any lawful purpose, including education and retrospective research on anonymous specimens. I understand that my procedure may be observed, recorded or videotaped for medical education or consultation purposes. Efforts will be made to protect my confidentiality and privacy during any recording, videotaping process, or distribution of tissues. I understand I have the right to refuse such observation, recording, videotaping or use of tissues. My decision will not influence the choice of operation/procedure or the way in which it is performed. I understand that the quality of care I receive at this hospital will not be affected in any way if I decide not to participate.

I have had an opportunity to ask questions and I consent to the treatment/procedure.

(7)_____ _____ **(3)**_____ _____
Signature of Person Witnessing Patient's Signature — Date/Time — Signature of Patient or Authorized Representative — Date/Time

If Authorized Representative, print name and relationship to patient: _____

If interpreter utilized, Name of Interpreter: _____

If consent is obtained by telephone:

_____ _____ _____
Signature of Witness — Printed Name of Witness — Date

Instructions for completing this form can be found on reverse.

GENERAL GUIDELINES FOR COMPLETING CONSENT FORM
Please refer to the UMMMC Policy and Procedure for a detailed discussion of the Informed Consent process.

DEFINITION OF INFORMED CONSENT
Informed consent involves a process of effective communication and Disclosure during which the physician, or other health care provider assisting the physician, must provide to patients (or their authorized representatives) information they require in order to make knowledgeable decisions about the proposed treatment. The physician's explanation of the proposed treatment should include:

- The nature of the patient's condition
- The proposed treatment and possible alternatives, including the alternative of no treatment
- The benefits of the proposed treatment and its alternatives
- The nature and probability of risks of the proposed treatment and its alternatives, including the alternative of no treatment and
- The inability of the physician to guarantee results, and the irreversibility of the procedure, when applicable.

HOW TO COMPLETE THIS FORM

1. Procedures Requiring Consent
Written informed consent must be obtained every time a procedure is performed unless the procedure consists of a course of continuous and ongoing regularly scheduled treatments (e.g. chemotherapy, phototherapy, hemodialysis). In such cases (as long as there is no change in the nature of recommended therapy or other change in circumstances), informed consent need only be obtained once at the outset of the course of treatment. Certain medical/surgical interventions may require procedures by two or more independent specialists (e.g. radiographic localization for breast biopsy followed by breast biopsy). Since each component procedure carries its own risks, a separate informed consent form should be completed for each procedure. Routine procedures (e.g. IM injections, routine blood tests) are covered by the general consent process that occurs when patients are admitted to our inpatient or emergency departments.

2. Attending Physician Directing Treatment Plan or Procedure/ Provider Performing Procedure
Enter the name of the Attending Physician directing the treatment plan or procedure here . This Physician is legally responsible for ensuring that an informed consent process has occurred. Additional health care providers may assist the Physician in providing disclosure to patients and obtaining their written consent.

Provider Performing the Procedure: Enter the name of the practitioner who is performing the procedure. If the procedure is being performed by a resident, Nurse Practitioner or Physician Assistant without the direct supervision of the Attending Physician (in accordance with approved scopes of practice and delineation of privileges), then the name of the resident, NP or PA should be entered here. The Provider performing the procedure should then sign the form. Many times, the Attending Physician directing the Treatment Plan or Procedure will be the same as the Physician Performing the Procedure.

3. Authorized Representative: (if patient lacks capacity)

1. Guardian
2. Health Care Agent
3. Legal next-of-kin in the following order:
   a. spouse
   b. children of legal age
   c. parent(s)
   d. sibling(s) of legal age
   e. grandparent(s)
   f. aunt, uncle or first cousin (of legal age)

If the patient is competent but physically unable to sign the consent form, another individual may sign the patient's name at the patient's direction, followed by the initials of the individual signing. In this situation, the individual signing is not acting in the capacity of Authorized Representative.

4. Information Provided and Discussed
The Provider may document the material risks, benefits and alternatives discussed or reference/attach informational material. Any deviation from the standard or recommended procedure protocol, or modification of the terms of informed consent printed in this form should also be described in this section. Patient's comments or restrictions may also be documented in this section.

5. Date of Disclosure/Renewal of Consent
If the procedure is delayed by or repeated after 60 days beyond the signing of the informed consent form, the patient should be offered the opportunity to ask any additional questions about the procedure. However, if the procedure consists of a course of continuous and ongoing regularly scheduled treatments that extends beyond 60 days, review of consent is not necessary unless the circumstances change during the course of treatment. Record the date of any additional discussion here _____.
If circumstances change such that the risks and benefits of the proposed treatment are different or if the nature of recommended therapy has changed, a new informed consent form should be completed in order to document the nature of the changes.

6. Signature of Health Care Provider Providing Information to Patient
Although it is desirable that the disclosure be provided by the Attending Physician Directing the Treatment Plan or Procedure, there are circumstances in which this is not practicable. In such cases, another health care provider (specifically a Nurse Practitioner, Physician Assistant, Radiologic Technologists or Resident) may provide disclosure on behalf of the Attending Physician.

7. Person Witnessing Patient Signature
Any person at the direction of the Physician or UMMMC may witness the patient's signature and sign this section accordingly. Except for emergency situations, signatures should be obtained and this section should be completed before the procedure is performed.
Note: *For unemancipated adolescent patients between the ages of 14 and 18, it may be useful that a signature indicating the patient's assent to the procedure be recorded on this section of the form.*

PROCEDURES REQUIRING INFORMED CONSENT
As a general guideline, physicians should seek written informed consent for procedures meeting one or more of the following conditions:

1. it is invasive
2. it carries a material risk of complications, including morbidity and mortality
3. it is investigational*
4. it has a significant chance of a result differing from that desired by the patient and/or physician
5. it raises serious issues of patient confidentiality

All surgical procedures (whether performed in the Operating Room, Day Surgery Unit, ICU, Outpatient Department or Emergency Department) and the administration of general or regional anesthesia require written informed consent. Examples of the other procedures where written informed consent would be appropriate include:

angiography
angioplasty
arterial cannulation
arteriovenous hemofiltration
arthrocentesis
  joint injection
  joint aspiration
arthrography
biopsy: any tissue, any site
blood & blood component transfusion
bronchoscopy
cardiac catheterization/coronary angioplasty
cardioversion, elective
central venous cannulation
chemotherapy, parenteral
circumcision
cisternal tap
collagen injection
cryotherapy, cutaneous
cystoscopy
cystourethrography
dialysis, arterial and peritoneal
discography
electrodissection and curettage cutaneous
electrophysiologic studies (EPS), automatic cardiac defibrillator implantation myocardial catheter ablation
electroconvulsive therapy (ECT)
endoscopy
  gastrointestinal sphincterotomy or dilatation
  endoscopic treatment for bleeding
  colonoscopy
  sigmoidoscopy
epidural injection
esophageal dilation, manometry
exercise tolerance (stress) testing
fistulogram
genetic testing **
HIV testing **
hysterosalpingography
intrathecal administration of medicinal or diagnostic agents
labor and delivery (normal)
laryngography
laryngoscopy (direct)
lateral cervical procedure
lumbar puncture
lymphangiography
myelography
newborn intensive care
nerve block
pacemaker implantation, cardiac
  permanent
  transesophageal
  transvenous
paracentesis/intra-peritoneal injection
percutaneous needle or catheter placement under radiologic guidance, any site
pericardiocentesis
phototherapy
pneumoencephalography
radiation therapy
sialography
sodium amytal interview
subdural puncture
Swan-Ganz/right heart catheterization
thoracentesis, intrathoracic injection
transtracheal aspiration
T-tube cholangiography
urodynamics
venography
ventriculperitoneal (-atrial) shunt aspiration

* Note: Some investigational therapies may require completion of separate informed consent forms as directed by the Human Subjects Committee.

** This form is not utilized for these procedures; there are specific informed consent forms for HIV testing, genetic testing and anesthesia.

UMASS MEMORIAL MEDICAL CENTER
DEPARTMENT/DIVISION NAME

INFORMATIONAL MATERIALS
NAME OF PROCEDURE

NAME:

ADDRESS:

BIRTHDATE: SEX:

UNIT NUMBER:

PRINT CLEARLY IN INK OR STAMP WITH PATIENT CARD

Document risks, benefits and alternatives. Document any deviation from the standard or recommended procedure protocol, modification of the terms of informed consent printed on the informed consent form and patient's comments or restrictions, if any.

Item 1 Continued