UPMC
POLICY AND PROCEDURE MANUAL

POLICY: **HS-RI1302 ***
INDEX TITLE: **Risk & Insurance**

SUBJECT: **Patient Informed Consent**
DATE: **August 27, 2021**

I. POLICY/PURPOSE/SCOPE

It is the policy of UPMC to recognize an individual patient's right to be informed of and consent to procedures performed and treatments provided at UPMC facilities or at facilities where UPMC personnel may render care, including via telemedicine, in accordance with applicable law. This policy is intended to provide direction regarding informed consent law. The policy reviews the legal requirements for informed consent such as when informed consent is necessary, who may consent and the facility's documentation requirements. For purposes of this policy, the term "patient" includes a person authorized to consent on behalf of a patient who lacks decision-making capacity. The term "physician" shall also apply to "dentists" who are performing dental surgery. This policy applies to inpatients and outpatients of UPMC's Pennsylvania and New York provider locations, including the following UPMC hospitals.

[Check all that apply]

- ☒ UPMC Children's Hospital of Pittsburgh
- ☒ UPMC Magee-Womens Hospital
- ☒ UPMC Altoona
- ☒ UPMC Bedford
- ☐ UPMC Chautauqua
- ☒ UPMC East
- ☒ UPMC Hamot
- ☒ UPMC Horizon
- ☒ UPMC Jameson
- ☒ UPMC Kane
- ☒ UPMC McKeesport
- ☒ UPMC Mercy
- ☒ UPMC Northwest
- ☒ UPMC Passavant
- ☒ UPMC Presbyterian Shadyside
  - ☒ Presbyterian Campus
  - ☒ Shadyside Campus
  - ☒ UPMC Western Psychiatric Hospital
- ☒ UPMC St. Margaret
- ☒ UPMC Pinnacle Hospitals
- ☒ UPMC Carlisle
- ☒ UPMC Memorial
- ☒ UPMC Lititz
- ☒ UPMC Hanover
- ☒ UPMC Muncy
- ☒ UPMC Wellsboro
- ☒ UPMC Williamsport
  - ☒ Divine Providence Campus
- ☒ UPMC Lock Haven
- ☒ UPMC Cole
- ☒ UPMC Somerset
- ☐ UPMC Western Maryland

Provider-based Ambulatory Surgery Centers

☒ UPMC Altoona Surgery Center
☒ UPMC Children's Hospital of Pittsburgh North
☒ UPMC St. Margaret Harmar Surgery Center
☒ UPMC South Surgery Center
☒ UPMC Center for Reproductive Endocrinology and Infertility
☒ UPMC Digestive Health and Endoscopy Center
☒ UPMC Surgery Center – Carlisle
☒ UPMC Surgery Center Lewisburg
☒ UPMC Pinnacle Procedure Center
☒ UPMC West Mifflin Ambulatory Surgery Center
☒ UPMC Community Surgery Center

Free-Standing Ambulatory Surgery Facilities:

☐ UPMC Hamot Surgery Center **(JV)**
☐ Hanover Surgicenter
☐ UPMC Leader Surgery Center **(JV)**
☐ UPMC Specialty Care York Endoscopy
☐ Susquehanna Valley Surgery Center **(JV)**
☐ West Shore Surgery Center **(JV)**

Links to policies related to this policy can be found in Section IX.

II. INFORMED CONSENT UNDER PENNSYLVANIA and NEW YORK LAW COMPATIBLE

A. **Procedures Covered.** The law provides that except in emergencies, a physician owes a duty to obtain informed consent from a patient prior to the following:

1. Performing surgery.
2. Administering anesthesia related to the performance of surgery.
3. Administering radiation or chemotherapy.
4. Administering a transfusion of blood or blood products.
5. Inserting a surgical device or appliance.
6. Administering an experimental medication. (See Section VII).
7. Using an experimental device. (See Section VII).
8. Using an approved medication or device in an experimental manner (See Section VII).
9. Testing for human immunodeficiency virus (HIV) (See policy HS-RI1307 UPMC Voluntary Patient HIV Testing).

B. **Physician Communications with Patients.**

1. **Required Information**. For those procedures requiring informed consent, the physician or his/her designee should provide the patient the following information about the procedure that a reasonably prudent patient would require to make a decision as to that procedure: Abbreviations should not be used to denote a procedure.

   a. **Description of the procedure.** [**Practice Note:** Description should include a reasonably detailed explanation of procedure including purpose of procedure, body parts affected, and condition, disease or incapacity being treated.]

b. **Desired benefits of procedure.** [**Practice Note:** Do not inflate benefits or probability of obtaining benefits. No guarantees or assurances of obtaining benefits should be given.]

c. **The known risks associated with the procedure.**

1) Every potential risk need not be explained, only material risks.

a) those that are severe (e.g., death, neurological deficit), even if remote.
b) those that occur with some significant frequency, even if not severe.

d. **All medically viable alternatives to the procedure.**

1) Should include an explanation of the risks of the alternatives, including prognosis/risks if nothing is done.

2. **Goals and Recuperation.** Discuss the likelihood of the patient achieving his or her goals; and any potential problems that might occur during recuperation.

3. **Patient Questions.** Answer any reasonable questions the patient may have about the procedure.

4. **Procedure–Specific Consent Forms.** Develop procedure-specific forms and other written materials to help communicate required information, document patient receipt of information and document patient consent.

5. **Use of Understandable Language.** When communicating with patients verbally or in writing, use language that a typical patient can understand.

C. **When Obtaining Informed Consent Is Not Necessary.**

1. **Emergency Situations.** A procedure may be performed without obtaining informed consent if all of the following exist:

- a physician determines that a procedure requiring informed consent should be performed to preserve the life and/or health of the patient; and
- the patient is incompetent, is a minor or is otherwise unable to provided informed consent; and
- there is no time to seek consent from a parent, guardian or other acceptable substitute decision-maker; or reasonable efforts to do so have failed.

2. **Documentation.** The attending physician should document the need for proceeding with the procedure/treatment without consent and any efforts taken to secure consent from a substitute decision-maker (parent, guardian, next-of-kin, etc.).

III. WHO MAY OBTAIN INFORMED CONSENT

1. The attending physician overseeing the patient's care is responsible for ensuring that informed consent exists before all procedures that require informed consent but may delegate this duty to qualified fellows, residents, Advanced Practice Providers, such as Certified Nurse Midwives (CNMs), Certified Nurse Practitioners (CRNPs) and Physicians Assistants (collectively referred to as "APPs") and Certified Registered Nurse Anesthetists (CRNAs) when appropriate. The consent form documenting the consent discussion shall be signed by the provider obtaining consent.

2. **Nurses other than CRNAs, CNMs and CRNPs May Not Obtain Informed Consent.**

3. Nothing under this section shall be construed to require a physician to delegate the authority to obtain informed consent to a qualified practitioner or prohibit a patient or the patient's authorized representative from requesting the physician, rather than the delegated qualified practitioner under subsection II. B.1, answer a question concerning the procedure, risks, or alternatives to the procedure or obtain informed consent. If the patient or patient's authorized representative makes a request that the physician act under this subsection, the physician shall obtain informed consent.

IV. WHO MAY CONSENT

1. **Competent Adults.** "Competent" individuals 18 years of age or older have a right to give consent for medical care. "Competent" individuals are defined as those who, when provided appropriate medical information, communication supports and technical assistance, (1) understand the potential material benefits, risks and alternatives involved in a specific proposed health care decision; (2) make that health care decision on their own behalf; and (3) communicate that health care decision to any other person. In other words, they possess decisional capacity with respect to the decision in question. The term is intended to permit individuals to be found competent to make some health care decisions, but incompetent to make others. In the case of a patient who is conscious, alert, and oriented, decisional capacity for medical decisions can be presumed unless circumstances call the presumption into question.

2. **Decisional Capacity**.

   a. Basic elements of decisional capacity include the ability to communicate, understand and appreciate information about risks, benefits, and alternative treatments.

   b. Medical conditions which may impair a patient's decisional capacity include drug intoxication and withdrawal, delirium, dementia, intellectual disability, psychosis, and mood disorders.

   c. Decisional capacity is frequently judged on a sliding scale based on the risk and benefits of the decision. As a decision to initiate treatment is often low risk with relatively high benefit, patients may be able to sign a TPO despite mild impairment.

   d. Questions as to whether a patient has or lacks decisional capacity for decision making competency should be directed to the patient's attending physician or designee. The physician's opinion regarding the decisional capacity for medical decisions of a patient should be documented in the patient's record. A physician may obtain an ethics or psychiatric consult to assist with the evaluation of decisional capacity for medical decisions.

   e. Lack of decisional capacity for medical decisions may be transient and may need to be reassessed periodically.

3. **Substitute Decision-Makers for Incompetent Adults.** All decisions made by substitute decision makers should be documented in the patient's medical chart.

   a. **Guardian or Other Court Appointed Substitute Decision-Maker.** Consent may be given by a patient's court-appointed guardian or other person granted powers by a court to make medical decisions for the patient. A copy of the Order of Court appointing the guardian or granting the medical decision-making powers should be obtained prior to the procedure and made a part of the patient's record. A guardian may not admit an incapacitated person to an inpatient psychiatric facility. A guardian may consent to Electroconvulsive therapy (ECT) if specifically stated in an Order of Court.

   b. **Agent Appointed Through Power of Attorney.** Consent may be given by a person (Agent) who is given powers to make medical or other treatment related decisions for the patient in a valid "Power of Attorney." A Power of Attorney: 1) can be general or specific, 2) grant full powers or limited powers 3) address financial matters, health care matters or mental health care matters. A Power of Attorney for making health care or mental care decisions requires the patient to lack capacity before becoming effective. Also, before the Agent can act on behalf of the patient, he or

she must execute a written document that complies with Pennsylvania and New York law acknowledging his or her obligations as an Agent. A copy of the Power of Attorney and written Acknowledgment should be obtained prior to the treatment of the patient, reviewed to determine its specifications and limits, and made a part of the patient's record.

c. **Agent Appointed by Advance Directive.** If the patient is in a permanent vegetative state or has a terminal condition, a person given the authority by the patient's advance directive (living will) may provide consent for health care decisions. A copy of the Advance Directive should be placed in the patient's medical record.

d. **Health Care Representatives**. When the patient does not have a guardian or other court-appointed substitute decision-maker, agent appointed through power of attorney, or agent appointed by advance directive, or if any of these designated substitute decision-makers are not reasonably available, the patient's health care representative may become the patient's substitute decision maker. The health care representative may make health care decisions and provide consent on behalf of patients, except for decisions to withdraw or withhold life-sustaining treatment from patients who do not have end-stage medical conditions or are not permanently unconscious. A Health Care Representative differs from the Personal Representative selected by the patient and who has a limited role which is defined in HS-MR1000.

The statutory order of priority provides that any member or members of the following classes, in descending order of priority, who is/are reasonably available, may act as the health care representative(s):

i. the spouse, unless an action for divorce is pending, and the adult children of the patient who are not the children of the spouse;
ii. an adult child;
iii. a parent;
iv. an adult brother or sister;
v. an adult grandchild;
vi. an adult who has knowledge of the patient's preferences and values, including, but not limited to, religious and moral beliefs, to assess how the patient would make health care decisions.

Additionally, neither a patient's attending physician or other health care provider, nor an operator or employee of a health care provider in which the patient receives care, may be a health care representative unless related to the patient by blood, marriage or adoption.

In many instances, there may be multiple individuals that qualify as health care representatives within the same class, e.g. multiple siblings or multiple adult children.

i. As a practical matter, if the health care representatives agree and consent to treatment as recommended by the patient's physician(s) and the involved health care providers consider the treatment to be reasonable and in the best interest of the patient, the treatment may be carried out. As many of the involved and readily available family members as possible should sign the consent form or give consent by telephone. A note should be placed in the patient's record documenting the consent of the involved family members.

ii. If there is disagreement among healthcare representatives, physicians and hospital staff should strive to help them build consensus when possible. However, law provides that the attending physician or health care provider may rely on the decision of a majority of these individuals. Physicians and hospital staff are also strongly encouraged to consult with the Ethics Consultative Service and Corporate Legal Department prior to applying the terms of the statute.

iii. If no agreement can be reached, a court appointed guardian should be considered.

For more information concerning the selection of a health care representative and the rights of such representative to provide informed consent on behalf of a patient, please see UPMC's Policy HS-PS0506 Guidelines for Life-Sustaining Treatment. Patients lacking capacity may not have a surrogate decision maker consent to Electro Convulsive Therapy. A separate court order is required.

e. **Individual With Intellectual Disability Residing in a State-Operated Facility for Persons with Intellectual Disability.** The Pennsylvania Mental Health and Intellectual Disability Act of 1966 provides that the facility director of the state-operated facility may consent to certain health care procedures after receiving advice from two physicians not employed by the facility housing the patient, for example a UPMC primary care physician and a specialist.

f. **Decision Not in Best Interest of Patient**. If the substitute decision-maker(s) request a procedure/treatment that is not recommended by the patient's treating physician(s), or if any health care provider questions whether the decision is in the best interest of the patient, the decision should not be carried out without consultation with Corporate Risk

Management or the Corporate Legal Department. An ethics consult may be helpful to resolve the issue.

4. **Decision-Makers for Minors.** (After consideration of the following guidelines, each facility or organization shall develop a process for obtaining consent for treatment to be performed on minors and incorporate those procedures into any policies or procedures related to Consent for Use and Disclosure of Information for Treatment/Payment/Health Care Operations.)

   a. **Parents.** A parent must consent to a treatment performed on a minor (patient under 18 years of age) **except** when the parent has:

   - permanently or temporarily given up parental rights;
   - parental rights have been taken away by court order;
   - the minor has rights under informed consent law to consent to treatment without parental involvement (see subsection 6, below, for specific examples): or
   - the parent has temporarily given another competent adult the power of attorney to make medical decisions for the minor by way of a written document in compliance with informed consent law.

   Unless there is some reason to doubt the status of a person purporting to be the parent of a minor with authority to consent for the minor, the purported parent's consent may be accepted without further proof or documentation. However, if there is any doubt as to the person's parental status or authority to consent for the minor, further proof or documentation should be obtained and made a part of the medical record.

   i. **Natural Parents**:

   - If adult parents are married and no court has altered any parental rights, either parent may consent.
   - If adult parents are divorced, either parent may consent provided their parental rights have not been restricted by court order.

   - For a child born to unmarried adult parents:

     - The unmarried adult mother may consent.
     - The unmarried, adult father may consent only if he has filed with the Pennsylvania Department of Human Services an acknowledgment of paternity for the child that includes the consent under oath of the natural mother (supported by her affidavit).

- For a child born to minor parents:

  - A minor mother may consent for her child.
  - A minor father may consent for his child only if

- He is married to the mother at the time of the birth of the child; or
- He is or has been married and he has filed with the Pennsylvania Department of Human Services an acknowledgment of paternity for the child that includes the consent under oath of the natural mother (supported by her affidavit).

ii **Adoptive Parents**:

- If adoption is final, adoptive parents have all rights of natural parents and may consent with the same limitations as natural parents.

- If adoption is not final:

  - If a decree terminating the rights of a natural parent has not been entered, the natural parent retains the right to consent unless that right has been taken away or limited by court order.

  - If a court decree terminating rights of both natural parents has been entered, consent must be obtained from the person(s) or agency appointed legal custodian/guardian in the court decree that terminated the rights of the natural parent(s). A copy of the court decree should be obtained prior to the procedure and made a part of the record.

5. **Persons Granted Power of Attorney for Health Care of a Minor.** A parent, legal guardian or legal custodian of a minor may authorize an adult relative or family friend to consent to treatment to be rendered to the minor under the supervision of or upon the advice of a physician, nurse, school nurse, dentist, mental health or other healthcare professional. The authorization must be in writing and in compliance with Pennsylvania's Medical Consent Act and New York law. A copy of the authorization should be obtained prior to the procedure and made a part of the record.

6. **Instances When Minors Can Consent**. All information that supports the right of a minor to consent without parental involvement (e.g., marriage, military service, etc.) should be documented.

a. A minor

- who has graduated from high school;
- who has been pregnant; or
- who has been married

may consent to treatment and the consent of no other person is necessary

b. A minor may consent for diagnosis or treatment of pregnancy, venereal disease, or any other disease reportable to the State Department of Health. (NOTE: A minor's consent to pregnancy termination is not valid without parental consent unless authorized by Court Order.)

c. A minor who has problems with substance or alcohol use may consent to evaluation and treatment for substance use disorders.

d. A minor who is 14 years of age or older, believes he or she is in need of mental health services and substantially understands the nature of voluntary treatment, may consent to examination and treatment for mental health services.

e. A minor who is at least 17 years of age may donate blood in any voluntary non-compensatory program.

f. A minor "emancipated" by Court Order may consent to all medical procedures and treatment allowed by the Court Order. (A general emancipation would authorize the minor to consent to all medical procedures.)

g. A minor who is "emancipated" from his parents by circumstances; i.e., the minor lives apart from his parents and is independent of parental control and financial support; has the right to consent to health care without parental involvement. An example of a minor "emancipated by circumstance" would be a minor serving in the military. Whether a minor is emancipated by circumstances depends on the particular facts of the minor-parent relationship. Those facts that support the minor's asserted right to "emancipation" should be documented on the consent form and/or elsewhere in the medical chart. Any questions concerning the "emancipation" of a minor should be referred to Risk Management or UPMC Corporate Legal Department.

V. REFUSAL TO CONSENT

A. After consideration of the following guidelines:

1. **Competent Adults**. As a general rule, a competent adult patient may decline any treatment or procedure, even if the treatment is considered to be medically appropriate or necessary.

2. **Substitute Decision-Makers for Incompetent Adults.** A substitute decision-maker for an incompetent adult patient (guardian, agent with power-of-attorney, healthcare representative) may refuse a treatment or procedure on behalf of an incompetent patient. If the treatment or procedure is considered appropriate and necessary to preserve the health or life of the patient and a treating physician or other health care provider believes the refusal is NOT in the best interest of the patient, the matter should be taken to an appropriate administrative department (e.g., Risk Management, Legal, etc.). In certain cases, court intervention may be considered.

3. **Substitute Decision-Makers for Minors.** A parent, guardian or other legally recognized substitute decision-maker for a minor may refuse a treatment or procedure on behalf of the minor if the decision is in the best interest of the minor and does not significantly jeopardize the health or life of the minor. If a proposed procedure or treatment is considered appropriate and necessary to preserve the health or life of the minor and a treating physician or other health care provider believes the refusal to undergo the procedure or treatment is NOT in the best interests of the minor patient, the matter should be taken to an appropriate administrative department (e.g., Risk Management, Legal, etc.) In certain cases, court intervention may be considered.

4. **Documentation of Refusal.** If a patient or substitute decision-maker refuses a procedure or treatment, the refusal should be documented in the patient's record. The documentation should include the explanation of the procedure/treatment and the viable alternatives and consequences of refusing the proposed procedure/treatment that were discussed with the patient or substitute decision-maker.

VI. FACILITY DOCUMENTATION OF INFORMED CONSENT

A. **Facility Obligation**. It is the independent responsibility of each health care facility to verify that the informed consent of the patient was obtained by a physician or his/her designee prior to permitting the use of the facility for the performance of any procedure requiring informed consent.

B. **Facility Form**. An approved facility consent or procedure specific consent form should be used to document that the patient discussed the procedure with the physician or designee and that the patient consented to the procedure after being advised of the risks and alternatives.

C. **Procedures**.

1. **Obtaining Patient Signature**. Prior to administering any pre-procedure medication, it should be determined that the facility consent or procedure specific consent form has been properly completed, signed and witnessed.

   a. If the patient's competence is in doubt, a physician should be consulted.
   b. The physician obtaining the consent should involve an interpreter or translator when appropriate.
   c. A family member or other person may be included in the process if the patient requests.
   d. The patient may modify the consent form to reflect any reasonable limitations to service requested by the patient, so long as the modifications are acceptable to the facility, the physician ordering the procedure and/or the physician performing the procedure.
   e. The witness's signature attests only that the witness observed the patient sign the consent form or that the patient acknowledged to the witness that the signature on the form is the patient's if the form was not signed in the presence of the witness.
   f. If the consent form has not been signed prior to the administration of any pre-operative medication, the appropriate physicians and/or administrators must determine if, how and when the procedure will be undertaken.

2. **Completion of Initial Investigation Event Report.** An Initial Investigation Event Report should be completed and filed if there is any significant issue involving the patient's consent, including the patient's refusal to sign a facility consent form or procedure specific consent form.

D. **Verbal Consent of Patient.** Verbal consent may be accepted if the patient is competent, but is unable to sign the consent form due to some permanent or temporary disability. The verbal consent should be witnessed by a staff member who listens to the physician or designee obtaining consent from the patient. Documentation should include the signature of the witnesses and the reason the patient is unable to sign the form.

E. **Consent From Substitute Decision-Maker(s) Not Present to Sign Facility Form.**

1. **Obtaining Consent by Telephone.** If a patient is incompetent to consent and the patient's substitute decision-maker (parent, guardian, etc.) is unable to come to the facility to sign the consent form, telephone consent or consent by execution of the facility's consent form transmitted by facsimile or electronic means may be accepted if carried out in accordance with the facility's policy. The telephone consent should be confirmed by a

staff member who listens to the physician or designee obtaining consent. The facility should assure adequate witnessing, verification and documentation of telephone consents and the acceptance of written consent forms received by telefax and electronic transmission.

2. **Documentation.** Medical record documentation recommendations for telephone consent include the following:

   a. the date and time of the call
   b. the identity, relationship, and authority of the individual giving informed consent.
   c. the reason why telephone consent was necessary
   d. the identity of the person who witnessed the call
   e. a description of the information conveyed
   f. any question asked by the person
   g. the decision to consent.

3. **Electronic Mail**. Consents communicated only by electronic mail (i.e., where a signed facility consent form is not also received) should not be accepted.

F. **Life of Consent Form**. Consents for Surgery/Special Procedures are valid for 90 days except for any change in patient's condition (i.e., change in patient's physical/mental status) or change in planned procedure(s). One consent form may be sufficient for a series of preplanned repeat procedures (e.g., multiple returns to the OR for wound debridement/V.A.C. dressing change, transfusions) in which case the form may be valid for 1 year unless there is a change in the patient's condition that might alter the diagnostic or therapeutic decision. If that occurs, then consent must be reobtained.

VII. CONSENT TO RESEARCH, THE USE OF EXPERIMENTAL DRUGS OR DEVICES OR THE USE OF AN APPROVED DRUG OR DEVICE IN AN EXPERIMENTAL MANNER

A. **IRB Approval**. Research activities involving patients may only be carried out subject to the approval and pursuant to the requirements of the appropriate Institutional Review Board (IRB).

B. **Obtaining Consent**. It is the responsibility of the principal investigator/ physician or designee to obtain the patient's informed written consent (on a form approved by the appropriate IRB) to participate in research, which includes the use of experimental drugs and devices and the use of an approved drug or device in an experimental manner.

C. **Inquiries**. Questions concerning research may be addressed to the principal investigator of a specific research project, the appropriate IRB, P&T Committee or UPMC Corporate Legal Department.

VIII. PROCEDURES REQUIRING SPECIAL CONSENTS/COURT ORDER

A. Procedures and forms that comply with the relevant laws and regulations regarding consents for autopsies, abortions, sterilizations, mental health procedures, and other procedures for which specific legal requirements exist may be facility specific. Questions concerning consent should be directed to the appropriate facility or UPMC Corporate Risk Management.
NOTE: In Pennsylvania, an abortion is defined as "[t]he use of any means to terminate the clinically diagnosable pregnancy of a woman with knowledge that the termination by those means will, with reasonable likelihood, cause the death of the unborn child except that, for the purposes of this chapter, abortion shall not mean the use of an intrauterine device or birth control pill to inhibit or prevent ovulation, fertilization or the implantation of a fertilized ovum within the uterus." UPMC Magee-Womens Hospital and UPMC Harrisburg are the only UPMC facilities with a license to perform voluntary abortions.

B. No one may consent for abortion or sterilization for an incapacitated person without having a court order providing them with specific authority.

IX. POLICIES RELATED WITHIN THIS POLICY

HS-PS0506 Guidelines for Life-Sustaining Treatment

HS-RI1307 UPMC Voluntary Patient HIV Testing

SIGNED: Richard P. Kidwell
Senior Associate Counsel/Vice President of Risk Management
ORIGINAL: April 22, 2004
APPROVALS:
Policy Review Subcommittee: August 12, 2021
Executive Staff: August 27, 2021
PRECEDE: July 28, 2020
SPONSOR: Senior Associate Counsel/Vice President of Risk Management

*** With respect to UPMC business units described in the Scope section, this policy is intended to replace individual business unit policies covering the same subject matter. In-Scope business unit policies covering the same subject matter should be pulled from all manuals.**