POLICY NUMBER: CP02.010
CATEGORY: Patient Care

TITLE: Informed Consent for Treatment

POLICY: In general, consent should be obtained prior to any treatment or procedure. The UF Health Shands Consent and Authorization form provides general consent for diagnostic procedures and medical treatment, and prescription of medicinal drugs. Nevertheless, specific written Informed Consent must be obtained by the Patient's Attending Physician or her/his Physician-designee or a credentialed Advanced Practitioner with privileges to perform the procedure prior to any medical/surgical, diagnostic, or therapeutic procedure or treatment: (1) that entails Significant Risk to the patient or (2) for which Informed Consent is otherwise required by law, regulation or this policy.

PURPOSE: To identify procedures and treatments that require specific written Informed Consent and provide guidelines for documentation.

APPROVED:

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DEFINITIONS

A. Adult – A person 18 years of age or older.

B. Attending Physician – The physician primarily responsible for the patient's care.

C. Authorized Representative – The person authorized to consent for medical treatment of a Minor patient or incapacitated adult patient as set forth in this policy.

D. Emergency – A medical condition manifesting itself by acute symptoms of sufficient severity, which may include severe pain, such that the absence of immediate medical attention could reasonably be expected to result in any of the following:

   1. Serious jeopardy to the patient's health.

   2. Serious impairment to bodily functions.

   3. Serious dysfunction of any bodily organ or part.

E. Incapacitated or Incompetent – Means the physical or mental inability to communicate a knowing health care decision, as determined and documented by the Patient's Attending Physician. An adult patient is presumed to be capacitated unless there is written Physician (M.D. or D.O.) documentation to the contrary in the medical record.

F. Informed Consent – Means consent voluntarily given by a person after sufficient explanation and disclosure of the subject matter involved to enable that person to: 1) have a general understanding of the treatment or procedure and the medically acceptable alternatives (including non-treatment), including the substantial risks and hazards inherent in the proposed treatment or procedures; and 2) make a knowing health care decision, including the refusal of treatment, without coercion or undue influence.

G. Minor – A patient under the age of 18 years.

H. Physician – For the purposes of this policy, unless noted otherwise, the term Physician shall include medical and osteopathic physicians, dentists and podiatrists.

I. Physician-designee – Means another physician designated by the patient's Attending Physician to explain the procedure to the patient and obtain the patient's informed consent for the procedure and may, if appropriate under the circumstances, be a resident physician or an Advanced Practitioner credentialed to perform the procedure.

J. Proxy – A competent adult who has not been expressly designated to make health care decisions for a particular Incapacitated individual, but who is authorized pursuant to state statute to make health care decisions for such Incapacitated individual.

K. Significant Risk – A procedure is a Significant Risk procedure if it entails more than a minimal risk to the patient. In determining whether a procedure entails Significant Risk, the Physician should give consideration to the frequency of any potential associated poor outcome and the severity of any such outcome. Blood transfusions, as well as any procedures requiring anesthesia (general or regional) or sedation are considered to entail Significant Risk for the purposes of this policy.

L. Significant Surgical Tasks – Significant Surgical Tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices, placing invasive lines, and other surgical tasks that carry a similar degree of risk or required skill level.

M. Surrogate – For purposes of this policy, a Surrogate is a person or person(s) acting on the behalf of the patient, including a parent, guardian, designated health care surrogate, a healthcare durable power of attorney, or Proxy.

CORE PROCEDURE:

I. Patient's Right to Refuse Treatment

A. A competent Adult patient has the right to refuse treatment. All persons, including Baker Act patients and intellectually disabled patients are presumed to be capable of making healthcare decisions for herself / himself unless she or he is determined to be incapacitated by his or her physician. Incapacity may not be inferred solely from the person's voluntary or involuntary hospitalization for mental illness or from her or his intellectual disability.

B. If a competent Adult patient refuses treatment, the patient's Attending Physician should make a note in the patient's chart documenting that she or he explained the risks, benefits and alternatives of treatment with the patient and the patient refused to consent to treatment. If a patient leaves the emergency room or the hospital, a request should be made of the patient to sign the Against Medical Advice (AMA) form (see CP02.023 – AMA, Refusal of Treatment / Hospitalization Against Medical Advice and also CP02.014 – Emergency Patients – Acceptance and Transfer).

C. Informed Consent Forms for Specific Treatments or Procedures

1. An appropriate consent form (in the format of one of the templates listed below) shall be used for all surgery and other procedures or treatments entailing Significant Risk. No changes may be made to the template forms without approval from UF Health Shands Legal Services.

a. Informed Consent for Invasive Procedure (English: 15-0526-0) and (Spanish: PS65054).

b. Informed Consent for Non-Invasive Procedure/Treatment (English: PS58958) and (Spanish: PS65056).

2. Executed Informed Consent forms shall be placed in the patient's medical record for all patients, including patients participating in research. Research related consent forms will be placed in the medical record unless the Institutional Review Board (IRB) determines that there is no clinical benefit to placing the consent form in the medical record and that there is a potential risk to the patient (e.g. insurability, confidentiality, etc.)

II. Obtaining Informed Consent for Specific Treatments or Procedures

1. The Patient's Attending Physician or his/her Physician-designee, is responsible for explaining the procedure or treatment, the medically acceptable alternatives, and the

substantial risks or hazards inherent in the procedure or treatment, as well as those associated with the medically acceptable alternatives, including a decision not to pursue the recommended procedure/treatment, to the patient or Surrogate in a manner that s/he can understand. The Patient's Attending Physician or Physician-designee shall document in the progress notes of the medical record that the Informed Consent discussion has been conducted and the outcome of the discussion, and assure that the Informed Consent form reflects the information discussed with the patient.

A Physician Assistant (PA), Advanced Practice Registered Nurse (APRN), Certified Registered Nurse Anesthetist (CRNA) and/or a Certified Anesthesiologist Assistant (CAA) may obtain informed consent for procedures within their scope of practice that they are credentialed to perform.

A nurse midwife is responsible for obtaining signed Informed Consent forms from pregnant mothers under the care of the nurse midwife.

In the case of Institutional Review Board (IRB) consent, the individual directed by IRB protocol is responsible for obtaining consent to participate in the IRB approved research/study; however, consents for procedures/treatments requiring Informed Consent must still be obtained by the appropriate Physician.

A. Abbreviations should not be used when completing the Informed Consent form.

C. If any portion of the Informed Consent form is not given or applicable, the Physician or the patient should strike through the inapplicable language and the patient and Physician should initial in the margin.

D. When a patient or Surrogate is non-English speaking, the need for clear communication is critical. The Physician/PA/APRN/CRNA/CAA seeking the Informed Consent shall obtain the assistance of an interpreter to aid in the patient's or Surrogate's understanding of the information being presented. (See CP01.020 – Special Needs Accommodations for Patients and Visitors). The fact that an interpreter was used and the name of the interpreter should be documented on the Informed Consent form.

E. A patient or Surrogate who is unable to write shall make a "mark" as his or her signature. The witness (es) to the signing shall use full signature.

F. If an adult patient's Surrogate is not available to sign the consent form, consent may be obtained by the patient's Physician/PA/APRN/CRNA/CAA by a telephone conference call including an Adult witness who is affiliated with the facility. Immediately following the telephone conversation, the Physician/PA/APRN/CRNA/CAA and witness shall complete the appropriate Informed Consent form, including date and time of conversation; name of individual giving consent and relationship to the patient, and a statement that consent was obtained via the telephone.

G. As to minor patients, all consents must be obtained in writing from a parent or Authorized Representative, unless otherwise allowed by this Core Policy CP02.010, such as in a medical emergency. In the case of a medical emergency, every effort will be made to secure a written consent upon the parent or Authorized Representative's arrival at the institution. See Emergency Treatment, CP02.010, Section VI.

III. Obtaining Signatures on the Informed Consent Form

A. Physician Signature – The Physician/PA/APRN/CRNA/CAA obtaining Informed Consent shall sign the Informed Consent form at any time after the consent discussion and before the procedure or treatment begins.

B. Patient or Authorized Representative Signature - At the time the Physician/PA/APRN/CRNA/CAA signs the Informed Consent form; the Physician/PA/APRN/CRNA/CAA should also have the patient or the patient's Authorized Representative sign the Informed Consent form.

IV. Witnessing Signature on the Informed Consent Form

A. An Adult who is not related to/affiliated with the patient, but who is affiliated with the hospital or health center shall witness the patient or Surrogate sign the Informed Consent form.

B. Witness signatures must include the full name of the individual(s) witnessing the patient/healthcare Surrogate/proxy signature on the Informed Consent form.

V. Verification of Completion of Informed Consent Form Prior to Procedure

Prior to commencement of the consented procedure or treatment, the Attending Physician or Physician-designee shall verify that the Informed Consent has been completed. This verification should also occur during the final "time out" verification process. See CP02.056 – Pre-procedure Verification Process (Universal Protocol).

VI. Emergency Treatment

Informed Consent for Emergency procedures/treatments of Significant Risk must be obtained from the patient or appropriate Surrogate; except that, in emergency situations when the patient is Incapacitated, and the patient's Surrogate cannot be immediately reached, the Patient's Attending Physician must document in the medical record the existence of the Emergency and that the proposed procedure is necessary to preserve the life or health of the patient. In such cases, the Attending Physician may proceed to treat the patient's Emergency condition without obtaining Informed Consent from the patient's Surrogate. Notification of the individual authorized to consent for the patient shall be accomplished as soon as possible.

VII. Persons Authorized to Give Consent (see Informed Consent Flowchart PS133445)

A. For Adult Patients

1. If an Adult patient is not incapacitated, consent should initially be sought from the patient, but a capacitated patient's Designated Health Care Surrogate may also give consent if the designation form indicates that the Surrogate's authority is noted as immediately effective.

2. If an Adult patient appears to not have the capacity to consent or is intellectually disabled:

a. The Patient's Attending Physician (M.D. or D.O.) shall evaluate a patient's capacity to give Informed Consent. If the Patient's Attending Physician concludes that the patient lacks such capacity, the evaluation and conclusion should be documented in the patient's clinical record.

b. If the patient has designated a health care Surrogate or healthcare durable power-of-attorney, consent must be obtained from the Surrogate/healthcare attorney-in-fact on behalf of the patient.

c. If the patient does not have a designated health care Surrogate/healthcare attorney-in-fact, consent may be obtained from any of the following individuals in the following order of priority (a note must be made in the chart indicating that the selected individual is acting as the patient's Proxy, and is willing and available to consent):

i. A court appointed guardian authorized by the court to consent to medical treatment, upon presentation of a valid court order;

ii. The patient's spouse;

iii. An Adult child, or if the patient has more than one child, a majority of the Adult children who are reasonably available for consultation;

iv. A parent;

v. An Adult sibling, or if the patient has more than one sibling, a majority of the Adult siblings who are reasonably available for consultation;

vi. An Adult relative of the patient who has exhibited special care and concern for the patient and who has maintained regular contact with the patient and who is familiar with the patient's activities, health and religious or moral beliefs;

vii. A close Adult friend of the patient who has signed a Close Friend Affidavit (PS45081).

viii. A clinical social worker licensed pursuant to chapter 491, Florida Statutes, or who is a graduate of a court-approved guardianship program. Such a proxy must be selected by the Ethics Committee and must not be employed by UF Health Shands. The proxy will be notified that upon request, a second Physician, not involved with the patient's care, will be available to assist the proxy in evaluating treatment. Decisions to withhold or withdraw life-prolonging procedures will be reviewed by the Ethics Committee. Documentation of efforts to locate proxies from prior classes (items i-vii above) must be recorded in the patient medical record. See CP02.098 – Appointment for Social Work Proxy for process to appoint a licensed clinical social worker proxy for a patient.

B. For Minor Patients

1. Except as otherwise provided in this policy or by court order, only a natural or adoptive parent (even if the parent is a Minor), a legal custodian, or a legal guardian has the power as provided by law to consent to medical care or treatment of a Minor. All consents for minor patients, whether Informed Consent or for ordinary care and treatment, must be written consent – unless otherwise provided in this policy. If a parent, legal custodian, or legal guardian is unavailable, see section B.3 and 4 below.

2. A Minor patient may give consent for her/himself if:

a. Married or previously married;

b. Seeking care or service related to her pregnancy, excluding termination, unless otherwise provided by law. (Consult with Legal Services for exceptions to consent requirements for termination of pregnancy for a Minor patient);

c. Seeking consultation or care for a sexually transmitted disease, including HIV; or

d. Voluntarily seeking treatment for drug/alcohol dependency (this does not include Emergency medical treatment for drug overdose).

3. If the natural or adoptive parent, a legal custodian, or a legal guardian is not available to provide Informed Consent on behalf of a Minor, only the following persons, in order of priority listed, may provide Informed Consent for the Minor (including consent for surgery and anesthesia):

a. A person who possesses a power of attorney granting authority to provide medical consent for the Minor executed after July 1, 2001, unless otherwise limited by the power of attorney.

b. A person who has been designated as a Health Care Surrogate for Minor (Form PS134222) executed after September 30, 2015.

c. A relative who has been awarded a Court Order for Temporary Custody by Extended Family.

4. Other persons who may consent to the medical care or treatment of a Minor: Any of the following persons, in order of priority listed, may consent to the ordinary medical care and treatment (including blood testing, preventive care, tuberculin testing and well child care, BUT NOT to surgery, anesthesia, or any procedure requiring written Informed Consent under this procedure), of a Minor who is not committed to Department of Children and Family Services or Department of Juvenile Justice or in their custody when, after a reasonable attempt, a person listed in paragraph 1 above cannot be contacted and actual notice to the contrary has not been given to the provider by the person:

a. The stepparent

b. The grandparent of the Minor

c. An Adult brother or sister of the Minor

d. An Adult aunt or uncle of the Minor

C. Minors in Custody of Department of Children and Family Services (DCF) and Department of Juvenile Justice (DJJ)

1. A parent or guardian provides consent for treatment unless restricted by a court order. DCF has authority to consent to ordinary medical care and treatment only (does not include surgery or anesthesia) if the Minor has been adjudicated dependent and placed by

court order in the legal custody of the Department. DCF must obtain a court order to consent for treatment beyond ordinary medical care.

2. A parent or guardian provides consent for treatment unless restricted by a court order. When a Minor has been placed by order of the court within the care and custody or under supervision of DJJ, the court may, after due notice to the parent or guardian, authorize DJJ to consent to ordinary medical care and treatment (does not include surgery or anesthesia). DJJ must obtain a court order to consent to anything beyond ordinary medical care. Documentation shall be made in the Minor's medical record that a reasonable attempt was made to contact a person who has the power as provided by law to consent as stated in paragraph 1 above.

D. For Forensic Patients

Forensic patients, those confined or incarcerated by local, state or federal authority, retain the same rights to consent or not consent to treatment and/or procedures as non-forensic patients. For an Incapacitated forensic patient, the incarcerating authority must be contacted to obtain directions regarding contacting the patient's surrogate/proxy. A hospital Social Worker will assist in contacting the appropriate authority.

VIII. Limitations on Persons Authorized to Consent

A. Unless specifically authorized by the patient in writing or by court order, designated health care Surrogates, health care attorneys-in-fact, and Proxies cannot consent for:

1. Sterilization;

2. Termination of pregnancy;

3. Experimental treatments that have not been approved by the Institutional Review Board;

4. Electroshock therapy;

5. Psychosurgery;

6. Admission to a mental health facility; or

7. Withholding/withdrawal of life-prolonging procedures for a pregnant patient prior to the 24th week of pregnancy.

B. Unless specifically authorized by the court, a court-appointed guardian with the right to consent to medical treatment for the patient cannot consent to

1. Sterilization;

2. Termination of pregnancy;

3. Experimental procedures or treatments; or

4. Withholding/withdrawal of life-prolonging procedures for a pregnant patient prior to the 24th week of pregnancy.

IX. Period of Validity of Consent for a Single Procedure

Informed Consent may be obtained up to 60 days prior to the anticipated procedure or treatment or anesthesia. The period of validity for Informed Consent shall be for the duration of the patient's hospitalization The Patient's Attending Physician or her/his physician-designee shall confirm upon arrival for the treatment or procedure that the patient's condition has not materially changed. A new and separate consent form must be obtained for each individual treatment or procedure, unless otherwise indicated on an approved consent template.

X. Consent for Consecutive Procedures and Multiple Related Procedures

A. Generally, a new and separate consent form must be obtained for each individual treatment or procedure. If, however, the treatment plan involves repeating the same procedure/treatment multiple times or multiple related procedures/treatments, a single Informed Consent may be used for the entire course of treatment, provided:

1. The risks, benefits and alternatives of the procedure(s), based upon the patient condition, remain unchanged throughout the course of treatment;

2. The course of treatment proceeds as planned; and

3. There is no change in the patient's condition that might alter the diagnostic or therapeutic decision.

B. The period of validity for an Informed Consent for consecutive procedures or multiple related procedures must be set forth on an Informed Consent form, which has been approved, by the UF Health Shands Multi-Disciplinary Document Review Committee and UF Health Shands Legal Services. The period of validity shall be appropriate for the consecutive treatments or multiple related procedures.

C. For special instructions regarding blood and blood product transfusions, see section XI below.

XI. Special Instructions for Certain Treatments and Procedures

A. Minors with Sexually Transmissible Diseases

1. A Minor may consent to testing, examination and treatment for a sexually transmissible disease. The fact of consultation, examination, and treatment of a Minor for a sexually transmissible disease is confidential and, unless otherwise provided by law, shall not be divulged in any manner. Therefore, no bills may be sent to a parent or guardian and the insurance of the parent or guardian may not be billed without the patient's consent.

2. The Physician/PA/APRN/CRNA/CAA may encourage the Minor to divulge the nature of the condition to her/his parent/guardian(s).

B. Sterilization

1. Female patients supported by federal funds such as Medicaid or Medicare must meet Department of Health and Human Services guidelines for sterilization. Appropriate federal/state forms should be completed.

2. For Incapacitated patients, see Section VIII, above, for limitations on persons authorized to consent to treatment for the patient.

C. Termination of Pregnancy

1. When termination of pregnancy is considered a consultation with the appropriate Physician in the Department of Obstetrics and Gynecology should be obtained.

2. Any patient who requests or requires a termination of her pregnancy must complete and sign a termination of pregnancy consent form. An ultrasound must be performed to confirm gestational age. The completed consent form shall remain in the medical record.

3. A termination of pregnancy in the last trimester of pregnancy shall not be performed unless two Physicians certify and document in the patient's medical record that a reasonable degree of medical probability exists that the termination of pregnancy is necessary to save the life or preserve the health of the mother, or the Patient's Attending Physician certifies in writing to the medical necessity for an Emergency termination in the third trimester and another Physician is not available for a consult.

D. HIV Test

1. Generally, the patient shall be notified orally or in writing that the HIV test is planned and that s/he has the right to decline the test. However, if the patient is not competent, is incapacitated, or is otherwise unable to make an informed judgment, written Informed Consent for an HIV test must be obtained from a legal guardian or Surrogate/DPOA/Proxy (see Core Policy CP02.087 – HIV Test – Consent). . Any questions regarding the need for obtaining consent should be directed to UF Health Shands Legal Services.

2. During the consenting process the patient must be informed that Florida law requires the reporting of all HIV positive results with patient identifying information to the county health department and must receive information about the availability and location of anonymous testing sites.

3. All pregnant patients must be offered the opportunity to have an HIV test. If the patient refuses such testing, a written refusal shall be obtained if possible, and no testing shall occur.

E. Blood and Blood Product Transfusions

1. For all blood transfusions, the patient's Attending Physician or his/her physician-designee must obtain informed consent and ensure that the Informed Consent for Blood Transfusion form (English:15-0525-0) & (Spanish: PS65405) is filled out and signed by the patient or the patient's representative.

2. The period of validity for Informed Consent for blood and/or blood products shall be for the duration of the patient's hospitalization, unless otherwise indicated on an approved unit specific Informed Consent form, provided:

a. The risks, benefits and alternatives of the procedure(s), based upon the patient condition, remain unchanged throughout the course of treatment;

b. The course of treatment proceeds as planned; and

c. There is no change in the patient's condition that might alter the diagnostic or therapeutic decision.

3. The period of validity for Informed Consent for blood and/or blood products in an outpatient setting is 60 days unless otherwise indicated on an approved informed consent form.

4. For refusal of blood transfusion, the patient's Attending Physician or his/her physician-designee must obtain refusal of blood transfusion and ensure that the Refusal of Blood Transfusion form (English: PS104958) & (Spanish: PS105997) is filled out and signed by the patient or the patient's representative.

5. Special Situations Regarding Minor patients whose parents or guardians refuse to consent to a blood transfusion:

a. When a blood transfusion is not likely to be necessary: When a minor is undergoing a procedure in which the necessity of a blood transfusion is possible, but not likely, and the parent or guardian will not consent to a blood transfusion, the "Understanding Regarding Refusal of Blood Transfusion for Minors" form (PS74832) may be signed by the parent or guardian and placed in the patient's medical record. **This form should not be used without first contacting UF Health Shands Legal Services.**

b. When a blood transfusion is likely to be necessary: When a minor is undergoing a procedure in which is the necessity of a blood transfusion is likely, and the parent or guardian will not consent to a blood transfusion, **contact UF Health Shands Legal Services.**

F. Alcohol and/or Drug Test

See CP01.077 – Alcohol and/or Drug Test

XII. For further assistance in issues regarding consent for treatment, the following may be called:

A. UF Health Shands Legal Services Department

B. Self-Insurance Program Office

ASSOCIATED POLICIES:

CP01.020 – Special Needs Accommodations for Patients and Visitors
CP01.077 – Alcohol and/or Drug Test
CP02.014 – Emergency Patients – Acceptance and Transfer
CP02.023 – AMA, Refusal of Treatment/Hospitalization Against Medical Advice
CP02.029 – Advance Directives
CP02.056 – Pre-procedure Verification Process (Universal Protocol)
CP02.087 – HIV Test – Consent
CP02.098 – Appointment of Social Work Proxy

KEY WORDS: Surrogate, Proxy, Minor, Capacity, Incapacity, Emergency