Policy: Informed Consent Policy
Type: Administrative (ADM) / Administrative
Applicable To: Newark Beth Israel Medical Center & Children's Hospital of New Jersey , RWJBarnabas Health Corporate Services, Children's Specialized Hospital, RWJ University Hospital Rahway, RWJ University Hospital Somerset, RWJ University Hospital, Trinitas Regional Medical Center, RWJBarnabas Health Behavioral Health Center, Jersey City Medical Center, RWJ University Hospital Hamilton, Monmouth Medical Center, Clara Maass Medical Center, Community Medical Center, Cooperman Barnabas Medical Center, Monmouth Medical Center, Southern Campus
Policy Owner: System Chief Medical and Quality Officer
Effective Date: 4/23/2024
Approved by: Chief Medical Officer Committee

1. **Policy Statement:**

This policy applies to informed consent for procedures, surgeries, anesthesia, and other therapies. Informed consent is a legal and ethical requirement in which physicians or Performing Providers and patients exchange information concerning a patient's condition and proposed treatment options. The process of informed consent underscores the relationship between the patient and the performing provider. The principle of consent recognizes that patients have a right to make an informed, voluntary decision about their care. A consideration to achieve a comprehensive discussion is the identification of a need and use of a qualified language (including sign language) interpreter, or use of a visual- or hearing-impaired device.

During the informed consent discussion, the Performing Provider must describe the following:

1. Nature of the proposed care, treatment, services, interventions or procedures.
2. Potential risks, benefits, and side effects related to alternatives, including the possible results of not receiving care, treatment, and services.
3. Likelihood of achieving goals.
4. Potential complications during recuperation.
5. Name of the practitioner performing the procedure
6. Different types of qualified medical providers who will participate in their operation and their respective roles.

Written informed consent forms shall aid in the documentation of the consent progress but does not take the place of the informed consent discussion between the Performing Provider and the patient or Surrogate Decision Maker, as applicable.

Individuals Authorized to Consent

1. Every adult (18 and older) patient is presumed to have capacity to make health care decisions unless determined otherwise by a physician to a reasonable degree of medical certainty,

2. The patient is the appropriate person to sign the consent form as long as they have decision-making capacity and is legally permitted to sign the informed consent form. A patient is deemed to lack capacity if they are afflicted with a mental or organic illness which substantially impairs their ability to understand and appreciate the nature and consequences of the treatment in question, including the benefits and risks of and alternatives to the treatment, and to reach an informed decision regarding whether to accept or refuse the treatment. Confusion in other respects, a general determination of incompetency, or disagreement with physicians and family members about treatment plans does not automatically mean a person lacks capacity. The provider must document in the medical record whenever the patient is deemed not to have medical decision-making capacity. This documentation should include the medical decision posed as well as how decision-making capacity was assessed.

3. All patients signing consents must be: (a) of legal age (i.e., eighteen years or older), (b) an emancipated minor, or (c) a minor permitted by law to consent. An emancipated minor is a minor who is self-supporting and court documentation is required to evidence such standard. Other minors who are permitted to consent to their own treatment are described and include, but are not limited to: married minors, minors seeking treatment for venereal disease, and minors seeking treatment for HIV.

4. If the patient is a minor or lacks capacity to give consent, the legal guardian or the closest available relative in the following order may sign the informed consent form:

    a. Court appointed guardian;

    b. Person designated by the patient, including a health care representative or health care proxy;

    c. Spouse, domestic partner, civil union partner;

    d. Adult children;

    e. Parents;

    f. Sibling;

g. Nearest next-of-kin.

5. In the event of unavailability of a responsible party, the Administrator- On-Call will be notified to aid in finding an appointed surrogate. A procedure should not be deemed an emergency solely for the inability of finding a surrogate.

Procedures Requiring Informed Consent

The informed consent form must be completed, signed, dated and timed by the patient or Surrogate Decision Maker, as applicable, for:

1. All surgical procedures performed in the operating suite;
2. All procedures requiring anesthesia, other than local anesthesia;
3. Invasive diagnostic procedures such as arteriogram, myelogram, liver biopsy;
4. Other procedures or medications identified to be high risk (including use of psychotropic and other high risk medications); and
5. Other procedures or treatments for which informed consent is required by law.

Informed Consent Forms

1. The purpose of the informed consent form is to memorialize the informed consent discussion. The form does not replace the discussion that must take place between the Performing Procedure and the patient, or Surrogate Decision Maker. All completed consent forms must be filed in the patient's medical record (paper or electronic).
2. The operative procedure site must be specified on the surgical consent form. When the specific site (level) is to be selected during the procedure, the alternative sites must be specified on the surgical consent form (e.g., arteriovenous fistula on upper arm or wrist).
3. A series informed consent is for a procedure or treatment that requires an informed consent in a serial manner, on multiple instances, over a pre-defined period of time not to exceed one year, when the risks, benefits, and alternatives are not expected to be different on the multiple encounters. Should the procedure or patient condition change over that interim, the provider must obtain informed consent again and complete a new consent document. (Ex. Dialysis, ECT, Infusions of Biologics, etc.)
4. Informed consent for specific procedures remains valid for a six months period until:
    a. revoked by the patient or surrogate,

b. there are significant changes to the patient's condition such that the substance of the informed consent including the risks, benefits, and/or alternatives may be different,

c. new information concerning the proposed intervention or alternative treatments have come to light in the intervening period such that the substance of the informed consent including the risks, benefits, and alternatives are different, or

d. sufficient time has passed that either the patient or the surgical performing provider deems that a renewed discussion is necessary.

e. If an informed consent is invalidated by any of the above, then a new informed consent discussion and signed form is necessary with the same requirements as for the initial process.

Obtaining Signatures on Consent Forms

1. The informed consent form must be completed, signed, by the patient or Surrogate Decision Maker. Dates and time of the signature is documented at time of signature.

2. The signature of the patient or Surrogate Decision Maker, as applicable, is obtained by the Performing Provider or competent provider that has clinical privileges to independently perform the proposed surgery/procedure. CRNA, Medical residents, fellows, APNs, PAs, and other health providers that will be involved in a procedure may contribute to the informed consent process under the Performing Provider's direction.

3. Only the Performing Provider can deliver the information, obtain consent, document in the medical record the discussion, and sign informed consent form.

4. The Performing Provider must sign the informed consent form certifying that they have provided the information necessary for the patient or the Surrogate Decision Maker, as applicable, to give informed consent.

5. A witness is only required for telephone or verbal consents as described in the sections below.

6. Epic EMR has several options on the signing of a consent form – see the job aid: eConsents in EPIC RWJBH tool.

7. Except in emergencies, when the intended procedure will take place in a location other than the patient's current location, the informed consent form must be fully completed and signed by all parties prior to the patient's receiving anesthesia. If an informed consent form is not signed prior to the procedure, the patient will not be taken into the operation/procedure room.

8. Informed consent may be signed outside of the hospital with e-consent or provide a legally producible copy provided to the Hospital prior to the procedure and incorporated into the medical record. If there is a material change in the patient's condition such that the risks and benefits previously discussed are impacted or different, a new informed consent discussion should be held and a new informed consent form signed.

Telephone Consent.

When the patient does not have capacity to provide informed consent and the Surrogate Decision Maker is not physically present, informed consent may be obtained by telephone or virtual encounter. A telephone consent may also be used when the encounter with the patient and the Performing Provider is by telephone or virtual (i.e. telemedicine).If it is necessary to obtain a telephone consent of a Surrogate Decision Maker or the patient, the Performing Provider must record in the patient's record on the informed consent form that permission was granted by telephone and must sign the informed consent form. A witness must participate in the discussion, then confirm that the patient or Surrogate Decision Maker provided consent and then sign the form. When the informed consent discussion occurs by telephone or virtual means, but the patient or Surrogate Decision Maker signs electronically (e.g. via MyChart) a witness is not necessary.

Verbal Consent.

A verbal consent may be given if the informed consent discussion occurs over a telephone or virtual encounter. A verbal consent may also be given if the patient is physically incapable or unwilling to sign the document; however, verbally consents in the presence of the witness and interpreter, if required. The performing provider must record in the patient's record on the informed consent form and in the medical record notes that permission was granted verbally. As applicable, the provider should document in the medical record the reason for obtaining virtual consent. The Performing Provider must also sign the form as otherwise provided herein.

Emergencies.

In life-threatening emergencies, when a decision must be made urgently, the patient is not able to participate in decision making, and the patient's surrogate is not available, physicians may initiate treatment under the principle of implied consent without prior informed consent. In such situations, the physician should inform the patient/surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines

Questions. Any questions regarding consents should be directed to the Hospital Risk Manager.

Definitions:

1. For the purposes of obtaining informed consent, the Performing Provider is defined as the one who can perform the listed procedures independently, as defined below:

a. A licensed professional who has credentials to perform the procedure without the requirement of supervision or direction, or

b. A trainee enrolled in a graduate medical education program who has been deemed competent to perform the procedure under the Accreditation Council for Graduate Medical Education (ACGME) classification of supervision of "oversight"

Oversight: the supervising physician is available to provide review of procedures/encounters with feedback provided after care is delivered.

Associated Procedures:

- Consent for Treatment and Disclosure of Treatment for Minors: Treatment for substance use, substance use disorder, alcohol use, and/or alcohol use disorder; Outpatient Mental Health Treatment
- General Consent
- Anesthesia Consent
- Chemotherapy

Resources:

The American College of Surgeons (ACS) Statements on Principles for Informed Consent

https://www.ama-assn.org/delivering-care/ethics/informed-consent

Job Aids: eConsents in EPIC RWJBH

Regulatory references:

The Centers for Medicare & Medicaid Services Interpretive Guidelines for Informed Consent **State Operations Manual (Rev. 151, 11-20-15)**

- §482.13 Condition of Participation: Patient's Rights
- §482.51 Condition of Participation: Surgical Services
- §482.24 Condition of Participation: Medical Record Services

Standards–The Joint Commission (RC.02.01.01, RI.01.03.01, RI.01.03.03, RI.01.03.05

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2. Acronyms:

CRNA	**Certified Registered Nurse Anesthetist**
LP	**Licensed Practitioner**
PA	**Physician assistant**
CMS	**Centers for Medicare and Medicare Services** https://www.cms.gov/
APN	**Advance Practice Nurse**
APP	**Advanced Practice Provider**

3. Related Documents:

Document Type	Document Name
Associated Procedures:	
Resources:	
Job Aids:	
Regulatory references:	