

Patient Consent Process

Standard PCC.03.00

Informed consent is obtained through a process defined by the hospital and carried out by trained staff in a manner and language the patient or their surrogate can understand.

Intent of PCC.03.00

Informed consent is crucial to high-quality patient care, as it ensures that patients understand the potential risks and benefits, and alternatives. The informed consent process respects patient autonomy and decision-making abilities. One of the main ways that patients are involved in their care decisions is by granting informed consent. To consent, a patient must be informed of those factors required to make an informed decision.

The consent process is clearly defined by the hospital in policies and procedures and includes documentation requirements. Relevant laws and regulations are incorporated into the policies and procedures. Informed consent may be required multiple times throughout the care process. Patients and families are informed as to which tests, procedures, and treatments require consent and how they can give consent; for example, verbal agreement or consent or signing a consent form.

Patients understand who can provide informed consent in addition to the patient, if applicable through laws, regulations, or culture. Designated staff members are trained on the informed consent process. Education is provided to patients and families as part of the process of obtaining informed consent for treatment and is provided in a language and manner the patient understands.

The hospital identifies situations in which a surrogate decision-maker may be involved in decisions about the patient's care. This is particularly true when the patient does not have the mental or physical ability to make decisions, when culture or custom requires that others make decisions, or when the patient is a child. When the patient cannot make decisions about their care, a surrogate decision-maker is identified.

Informed consent is a process. This process must align with local laws and regulations and professional norms. The process may occur over multiple conversations. A summary of these conversations must be documented according to hospital policy.

The hospital defines what information must be documented as part of the consent process in its policy; common elements in documentation requirements include the following:

- Name of the hospital
- Name of the test, procedure, or treatment covered by the informed consent
- Name of the responsible practitioner(s) performing the procedure(s)
- Signature of the patient or designee if the hospital or laws and regulations require a signed consent form
- Date and time consent is granted by the patient
- Statement that the procedure was explained to the patient or designee, including benefits, risks, and alternatives
- The likelihood of success, potential complications, the recovery process, and possible results of nontreatment
- Name, signature, and role of the person who explained the procedure to the patient or surrogate
- Name, signature, and role of the clinical staff member witnessing the consent if required

The hospital defines requirements and a process for granting emergency consent or when bypassing the informed consent process is acceptable. This may include the following:

- What situations would merit an emergency consent or bypassing the informed consent process (for example, to provide lifesaving treatment to an unconscious patient with no identification or contact information, when unable to reach a surrogate or guardian of a minor)

- Who is allowed to grant emergency consent or to determine when to bypass the informed consent process
- How to notify the patient or designee of the decision to grant emergency consent or bypass the informed consent process

When informed consent is required, informed consent must be obtained and documented prior to starting the treatment or procedure except in emergency situations.

The hospital clearly defines documentation requirements in its informed consent policy. Except in emergencies, the hospital will require an informed consent form signed by the patient or surrogate in accordance with local laws and regulations. However, all hospitals must clearly define what information is required and how documentation occurs; documentation is consistent with hospital policy. Documentation requirements may include the following:

- Where and how the informed consent process is documented in the patient medical record (for example, on a consent form or in a progress note)
- Date and time of documentation
- The information discussed with the patient or their designee as part of the informed consent process (for example, the name of the procedure or treatment, alternative treatments, risks and benefits of the proposed procedure or treatment, expected outcomes and common complications of the procedure or treatment)
- The name, signature, and role of the clinical staff member providing information to and receiving consent from the patient or their designee
- The name and signature of the patient or designee granting consent

Measurable Elements of PCC.03.00

1. ☉ The hospital develops a written policy and implements an informed consent process that includes at least the following:
 - Defining what information must be discussed and documented as part of the consent process
 - Identifying situations in which a surrogate decision-maker is necessary or allowed and who in addition to the patient can provide consent, in accordance with laws and regulations
 - Stipulating that the date and time must be documented as part of the consent process
 - Identifying and training staff who are permitted to obtain informed consent
 - Describing the process and requirements for obtaining emergency consent or bypassing the informed consent process
 - Documenting requirements for obtaining informed consent over the phone if permitted
(See also ACC.02.01, ME 5; COP.09.06, ME 1; COP.10.01, ME 1; PCC.02.00, ME 2)
2. ☉ Hospital policy identifies what tests, procedures, and treatments require consent, including, at minimum, the following:
 - Surgery
 - Anesthesia and sedation
 - Use of blood and blood products
 - Other high-risk procedures and treatments identified by the hospital
(See also ASC.02.03, ME 1; COP.09.06, ME 1; COP.10.01, ME 1; IPSG.04.00, ME 1)
3. The informed consent process and related education is provided in a manner and language the patient or surrogate decision-maker understands. (See also ACC.02.01, ME 4)
4. Informed consent is obtained in a manner consistent with the process outlined in hospital policy.