



## Informed Consent

<b>Site</b>	All CHB
<b>Setting/Population</b>	All Settings/All populations
<b>Clinician</b>	All Clinicians

Informed consent assures that the patient and/or the **patient's representative** is given information related to their care in a manner that is understandable to them. The informed consent process acknowledges the patient's right to ask questions and to make an informed and voluntary decision as to whether or not to undergo a proposed procedure, intervention or type of care.

### Policy

- Informed consent is obtained by clinicians who are credentialed and/or certified to perform the procedure or treatment.
- Telephone consent may be used when informed consent in person cannot be obtained due to extraordinary circumstances. When consent is obtained over telephone from the patient representative, the same information on the informed consent form is communicated verbally.
- Verify that consent is in the medical record prior to initiating treatment.

### Scope of Consent

- The scope of informed consent may apply to:
  - a one-time, single treatment or procedure,
  - routine care of a specific issue or condition, or
  - a series of treatments.
- When the treatment plan involves recurrent treatments and procedures, it is not always necessary to repeat the informed consent process unless there is a significant deviation from the original plan or the patient's condition or diagnosis changes from the initial intent of the consent.
- In a medical emergency
  - if possible, locate the patient's family and obtain consent; document these efforts in the patient's medical record,
  - provide treatment required immediately to preserve the life of the patient or to prevent the serious impairment of the patient's health, and
  - document the nature of the medical emergency in the patient's medical record.

### Duration of Informed Consent

- Consent is valid for the course of treatment. If there is a significant change in the patient's condition that would reasonably be expected to alter the diagnosis or

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plan, the consent is rescinded and the process is repeated for the subsequent treatment plan.

- Informed consent obtained at the time of an outpatient visit is valid for a period of one year provided the patient is being treated for the same or similar health concerns.

## Informed Decisions

- The patient (if over 18 years of age or deemed to have legal capacity as a mature or emancipated minor to make his/her own health care decisions), or patient representative is informed of the patient's health status and involved in developing a plan of care. The discussion includes but is not limited to:
  - nature of the proposed care;
  - potential benefits, risks, side effects or problems related to the proposed care;
  - the likelihood of achieving the goals of the proposed care;
  - reasonable alternatives to the proposed care along with relevant risks, benefits and side effects related to the alternative including possible results of not receiving the proposed care; or
  - when indicated, any limitations to confidentiality of information from or about the patient.

**Note:** If a patient or patient representative refuses treatment deemed necessary by the clinical team, consult the Office of General Counsel.

- The **patient representative** may be
  - a parent or guardian if the patient is **under the age of 18** years;
  - a court-appointed guardian with authority to make health care decisions for the patient; or
  - a health-care agent named by the patient in a health-care directive, health-care power of attorney or similar document.

**Note:** If patient representative(s) disagree about treatment, consult the Office of General Counsel.

- **A patient representative gives consent if the patient is**
  - under the age of 18 years and does not have legal capacity to make health care decisions or
  - deemed an **incompetent adult** and has appropriate legal authority.

**Note:** Under certain circumstances a patient younger than 18 years has legal capacity to make health care decisions. See **Special Circumstances Involving Informed Consent Reference Tool** for more information.

- **The clinician obtaining the consent must take reasonable steps to ensure that the patient and/or the patient's representative understand the information provided.**

**Note:** Informed consent documents for use with patients should be written at or below the fifth-grade level and in the primary language of the patient to the extent possible. Provide a qualified medical interpreter or reader to assist patients or patient's representatives with limited English proficiency, limited health literacy, and/or visual limitations.

## Consent Documentation

- **A properly executed informed consent document is consistent with hospital policies and** includes, but is not limited to:
  - name of the hospital where the procedure or other medical treatment is to take place;
  - name of the specific procedure, or other type of medical treatment, for which consent is being given;
  - name of the responsible clinician who is performing the procedure or administering the medical treatment;
  - statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's representative;
  - signature of the patient and/or patient's representative; and
  - date and time the informed consent was obtained by the clinician. This reflects the date and time the patient and/or patient's representative gave consent.
- **The clinician's signature on the informed consent documentation signifies that the following information was provided:**
  - the indications for, and description of, the [clinical treatments and procedures requiring informed consent](#);
  - material risks and benefits for the patient related to the surgery or other invasive procedure and anesthesia based on the available clinical evidence, as informed by the responsible clinician's clinical judgment;
  - treatment alternatives, including the attendant risks and benefits; and
  - the probable consequences of declining recommended or alternative therapies.

## Refusal to Consent

- A patient or patient representative may refuse treatment. The patient or representative will be informed of the specific potential risks associated with the informed refusal in a manner that is appropriate for their learning and communication needs. Refer to the [Patient and Family Bill of Rights](#) for additional information.
- The information provided as well as the informed refusal is documented in the patient's medical record.

**Note:** If a patient or patient representative refuses treatment deemed necessary by the clinical team consult the Office of General Counsel.

## Changing Consent

- The person providing consent may modify or withdraw his or her consent at anytime. If this occurs, the physician should not proceed with the proposed procedure unless and until another informed consent is obtained.

## Clinical Treatments and Procedures Requiring Informed Consent

- Absent a medical emergency, a signed informed consent form is required prior to performing any of the treatments listed below.

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- **Administration of blood or blood products** (if not related to the surgery/invasive procedure)
- **Chemotherapy**  
**Note:** For Non-Oncology Chemotherapy, the need for consent is guided by the [matrix](#) found on the pharmacy website.
- **Circumcision**
- **Experimental procedures or treatments**
- [Genetic Testing \(asymptomatic\)](#)
- **Major joint injections**
- **Moderate sedation, deep sedation and general anesthesia**
- **Organ Donation**
- **Radiation therapy**
- **Sterilization**
- **Termination of Pregnancy** (special form required and special rules apply; consult with Office of General Counsel)
- **All surgical or other invasive procedures** (not including simple laceration repair and minor dermatological procedures performed in outpatient settings and not separately coded or billed).

Surgical or other invasive procedures are those involving a skin incision or puncture including, but not limited to: open surgical procedures, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, and endoscopies.

**Examples of surgical or other invasive procedures:**

- Biopsy
- Major percutaneous aspiration of body fluids through the skin (e.g., bone marrow aspiration, arthrocentesis, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization)
- Cardiac procedures (e.g., cardiac catheterization, pacemaker implantation)
- Central vascular access device insertion (e.g., Swan-Ganz catheter, percutaneous intravascular catheter (PIC) line, Hickman catheter)
- Major dermatology procedures (e.g., biopsy, incision and drainage of abscess, excision and deep cryotherapy for malignant lesions)
- Electrocautery of skin lesion
- Major endoscopy (e.g., J-tube placements, nephrostomy tube placements)
- Interventional radiology procedures (e.g., percutaneous biopsy)
- Invasive ophthalmic procedures (e.g., procedures involving implants)
- Major laser therapy
- Major oral surgical procedures (e.g., permanent tooth extraction and gingival biopsy)
- Podiatric invasive procedures
- Renal Dialysis
- Skin or wound debridement performed in an operating room

**Note:** Venipuncture and intravenous therapy are not included.

## Implementation

The clinician who performs or orders the treatment or procedure or designee completes the following steps:

1. Provide the patient and/or patient representative with the information necessary to make [informed decision](#) about a proposed medical treatment or procedure.
2. Discuss information provided with patient and/or the patient's representative in language they can comprehend.
3. Complete consent documentation as described in the [Consent Documentation](#) policy statements above. Standard consent forms are available in the [Consent Form Library](#).

## Documentation

Place signed informed consent form in patient medical record. In the event of a medical emergency or refusal to consent, document the nature of the medical emergency or circumstances of the refusal in the patient's medical record.

## Related Content

### Policy and Procedure

- Clinical Investigation Policy and Procedure: [Informed Consent/Permission/Assent Process](#)
- Ethics Advisory Committee: [Guidelines for Do-Not-Resuscitate Orders](#)
- Radiology Department Policy and Procedure Manual: [Interventional Procedure Consent](#) (Authorized Radiology Staff).
- Infection Control Manual: [Reportable Diseases](#)

### Patient Care Manual

- [Advanced Directives](#)
- [Informed Consent: Solid Organ Transplantation—Donor](#)
- [Informed Consent: Solid Organ Transplantation—Transplant Recipient](#)

### Patient Care Tools

- Forms > [Consent Form Library](#)
- Glossary > [Informed Consent](#); [incompetent adult](#)
- References > [Clinical Treatments and Procedures Requiring Informed Consent Reference Tool](#)
- References > [Special Circumstances Involving Informed Consent Reference Tool](#)

## Document Attributes

<b>Title</b>	Informed Consent		
<b>Author</b>	Paula Moynihan, BSN, RN Jackie Berlandi, MS, RN, CNOR, NE- BC Jane Romano, MS, RN Diane Tubman RN, BSN, CPN	<b>Date of Origin</b>	06/00
<b>Reviewed/ Revised by</b>	Marcie Brostoff, MS, RN, Laura Bobotas, BSN, RN	<b>Dates Reviewed/ Revised</b>	6/01, 11/01, 06/03, 09/03, 09/08, 2/09, 12/10
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<b>Approved</b>	<b>Signature on file</b> <hr/> Eileen M. Sporing, MSN, RN, NEA-BC, FAAN Senior Vice President for Patient Care Operations, Chief Nursing Officer <b>Signature on file</b> <hr/> Robert Shamberger, MD Chair, Medical Staff Executive Committee		