Informed Consent Policy – SAMPLE

Subject: Verification of Informed Consent by Physician Healthcare Provider and Non Physician Healthcare Provider*

Number: 

Effective date: 

Supersedes SPP: 

Approved by: 

(Signature) Date 

Distribution: 

I. STATEMENT OF PURPOSE:

To establish guidelines to ensure that patients receive and understand information needed to evaluate treatment options, risks and benefits in order to give informed consent.

II. STATEMENT OF POLICY:

Every patient has the right to participate in an informed consent discussion. This means that the patient has the right to receive a complete explanation of the proposed medical/surgical treatment or procedure from his/her physician before deciding whether to consent to having the proposed medical/surgical treatment or procedure done. It is necessary that patient’s informed consent be obtained prior to the medical/surgical treatment. In order to provide informed consent, the patient must understand the nature and purpose of the proposed medical/surgical treatment or procedure, the risks, the benefits, the alternatives, and the consequences of foregoing the proposed medical/surgical treatment or procedure. This is a process and the conversation should be documented as such in the patient’s medical record along with the informed consent form.

A. Consent Is Required When:

1. All invasive procedures, including major or minor surgery involving an entry into the body, either through an incision or through a natural body opening;
2. All high-risk therapies/drugs;
3. All procedures in which general/spinal anesthesia is used and certain procedures in which a local anesthetic is used;
4. Medical procedures that involve more than a slight risk of harm to the patient or which may cause a change in the patient’s body, e.g., chemotherapy, diagnostic procedures involving contrast or dyes, administration of drugs that carry very serious or irreversible side effects;
5. Forms of radiology therapy;
6. Experimental procedures and clinical trials;
7. Electroconvulsive therapy;
8. Other procedures that the medical staff determines requires a specific explanation to the patient;
9. Test for HIV (unless a healthcare provider has been exposed to the patient’s bodily fluids inadvertently while caring for the patient or the patient’s bodily fluids);
10. Blood and blood product use; or
11. Any off-label use of medical devices or medications if there is a potential for significant risk.

B. Who Must Give Consent:
1. Adult Patients
   The consent of every capacitated adult patient should be obtained prior to treatment. For purposes of consent, competency may be defined as an ability to understand the nature and consequences of the proposed medical/surgical treatment or procedure.
   If the patient is not capable of giving consent because of incompetence or other incapacity, consent should be obtained from a person who is empowered to act on the patient’s behalf (e.g., patient advocate, legal guardian). If a guardian or patient advocate has been appointed, a copy of the guardianship, durable power of attorney or other authorizing document(s) needs to be included in the patient’s medical record.
   If the procedure is not a medical emergency, there is no one with the legal capacity to consent for the patient, and the attending physician determines that the patient is temporarily incapacitated, treatment should be withheld until the patient regains capacity. If the attending physician determines that the patient is permanently incapacitated or that it is medically inadvisable to delay treatment until the patient regains capacity, approval should be sought from a member of the patient’s immediate family. In the matter of life saving treatment and no family is available, the physician may make the decision supported by comprehensive medical decision-making documentation. When needed, consent from a family member should be sought in the following order of priority, subject to availability and time constraints: NOTE: State laws may differ in this regard. Be sure to review the specific law that applies in your state.
   a. Spouse
   b. Adult children
   c. Parent
   d. Adult siblings
   e. Other close relative or significant other

2. Minor Patients
   If patient is under the age of 18, then typically a parent, legal guardian, or person acting in loco parentis must sign the consent.
   Exceptions to this general rule may exist for the following: NOTE: State laws may differ in this regard. Be sure to review the specific law that applies in your state.
   a. Emancipated minors
   b. Treatment for substance abuse
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c. Treatment for sexually transmitted diseases
d. Contraceptive care
e. Prenatal care and treatment
f. Abortion
g. Mental health care and treatment

C. Emergency Situations:
When immediate treatment is required to preserve the life of a patient or to prevent an impairment of the patient’s health and it is impossible to obtain the consent of the patient or other legally authorized individual, the hospital and its physicians may render treatment that is necessary to preserve the patient’s health until such time as the patient (or an authorized representative) can give any consent that is necessary.

The physician must document in the medical record that an emergency exists and that immediate treatment is needed to preserve the life or prevent serious impairment to the patient’s health.

D. Refusal to Consent:
A competent adult patient has the right to refuse any medical or surgical procedure (including emergency lifesaving treatment). The patient will be informed of the consequences of the refusal. The patient’s refusal should be noted on the medical record and a release should be secured from the patient (if possible) to document that treatment would have been rendered if the patient had not refused. Informed refusal should be documented with the same care and detail as informed consent.

E. Duration of Consent:
Consent for a particular procedure, such as surgery, is generally effective until the procedure is performed (as long as the patient’s condition does not change), but should not be obtained more than 30 days before the contemplated procedure.

For patients undergoing repetitive treatment, such as renal dialysis or chemotherapy, obtaining consent for the series of treatments over a specified time frame is acceptable. Obtain a new consent if there is a change in the patient’s health status or the procedure and/or treatment that alters the risks and benefits, increases discomfort, or may result in side effects originally disclosed to the patient.

F. Methods of Consent:
1. Written Consent
   A properly signed consent form, obtained prior to treatment, is the most effective manner in which to prove a valid authorization for a medical/surgical procedure. The original of each consent form is kept in the patient’s permanent medical record. The signature of the patient or patient representative should be provided freely and of his/her own accord, and witnessed by at least one staff person.

2. Telephone Consent
   Circumstances may be such that the consent of an authorized representative of the patient needs to be obtained over a telephone in order to avoid a delay in treatment. The telephone conversation should be noted on the consent form,
indicating the time and nature of the consent, and, if possible, the conversation should be witnessed by two persons on the same telephone line.

G. Responsibility:
1. **Physician Performing Procedure**
   Physicians are responsible for:
   a. Providing the patient with appropriate information in terms and language that the patient understands – Describing the planned procedure includes, but is not limited to, the following:
      1. Diagnosis of illness being treated
      2. Nature/purpose of the proposed treatment
      3. [For hospitals] Whether physicians other than the operating practitioner will be performing important aspects/significant surgical tasks of the procedure
      4. [For critical access hospitals] The names of practitioners performing important aspects/significant surgical tasks of the procedure and the specific significant tasks they will perform
      5. Risks/consequences of treatment
      6. Benefits of the proposed treatment
      7. Feasible alternatives available
      8. Prognosis if no treatment is rendered
      9. Giving the patient the opportunity to ask questions and receive answers to the patient’s satisfaction
   b. Ensuring that all of above elements of the informed consent discussion are documented in the medical record as well as in an informed consent form

2. **Non-Physician Healthcare Provider**
   Non-physician healthcare providers are responsible for the following:
   a. Providing the appropriate forms for the medical/surgical treatment or procedure and ensuring that the appropriate consent form is present in the medical record before the medical/surgical treatment or procedure is commenced
   b. Reviewing the appropriate consent form and/or the supplemental documentation in the medical record – The following information must be included in the record:
      1. Patient identity;
      2. Diagnostic or therapeutic procedure/treatment;
      3. Name of individual performing procedure;
      4. [For hospitals] Whether physicians other than the operating practitioner will be performing important aspects/significant surgical tasks of the procedure;
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5. [For critical access hospitals] The names of practitioners performing important aspects/significant surgical tasks of the procedure and the specific significant tasks they will perform;

6. Coverage of the elements of a valid consent within physician discussion including:
   A. Diagnosis
   B. Nature/purpose of care to be provided
   C. Other significantly participating providers
   D. Risk/consequences of care
   E. Feasible alternatives
   F. Potential benefits
   G. Prognosis if no treatment is rendered
   H. Signature by person with capacity to consent

7. Patient/patient representative signature on form or appropriate documentation.

   c. Being available to witness the patient’s signature – The non-physician healthcare provider* is not responsible for securing the consent or ensuring that proper information was given to the patient or patient representative. However, immediately prior to having the patient sign the consent form, the non-physician healthcare provider should ask the patient the following questions:
      1. Have you read the consent form?
      2. Do you understand the consent form?
      3. Do you have any questions?

   d. Contacting the physician and appropriate department personnel if a signed consent form is not present in the medical record and/or the information listed in item 2 above is not evident in the medial record.

   e. Referring any patient questions regarding the elements of informed consent to the physician responsible for obtaining informed consent, before allowing the patient to sign the consent form.

   f. Delaying the procedure and/or having the patient sign the consent form until the physician responsible for obtaining informed consent has addressed all questions.

   g. Contacting the appropriate supervisor* or on-call administrator* if the responsible physician refuses or fails to respond to the non-physician healthcare provider* – The supervisor* will contact the appropriate section chief or chief-of-staff if further assistance is needed. The section chief or chief-of-staff is expected to respond in a timely manner to requests for assistance.
H. Miscellaneous

1. Signatures
   A legal signature is any mark intended to be a person’s signature. All signatures on any documents should be in ink, including the signatures of a witness and any other information written on the document.

2. Witnesses
   Employees who have reached the age of majority may legally sign as a witness. Employees will not become involved in the personal legal affairs of patients.
   Surgical consents, permissions for autopsy, and various releases from responsibility may be witnessed by a non-physician healthcare provider* or by an employee of the physician who is at least 18 years of age. Nursing students should not act as a witness.

*Indicates the need to insert the position name used in your organization.