SAMPLE: Verification of Informed Consent by Physician and Non-Physician Providers

Subject: Verification of Informed Consent by Physician and Non-Physician Providers
Number: 
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Approved by: (signature) 
Distribution: 

I. Statement of Purpose:
To ensure that patients receive adequate information to knowledgeably evaluate treatment options, risks and benefits, and to give informed consent

II. Policy:
Every patient has the right to informed consent, which includes receiving an explanation of a proposed medical/surgical treatment by a physician/provider and then agreeing or refusing to accept the proposed medical/surgical treatment.

It is necessary that patient’s consent be obtained before the medical/surgical treatment is provided/performed. Obtaining consent is a process and the process should be documented in the patient’s medical record. The consent must be informed; that is, the patient must understand the nature and purpose of the proposed medical/surgical treatment, as well as the risks, benefits and alternatives.

III. When Consent Is Required: (note: this list is not intended to be all inclusive and should be modified by the organization based on procedures performed)
- All invasive procedures including major or minor surgery involving an entry into the body, either through an incision or through a natural body opening
- All high-risk therapies/drugs
- All procedures in which general/spinal anesthesia is used and certain procedures in which a local anesthetic is used
- 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 with a potential for very serious or irreversible side effects)
- Forms of radiology therapy
- Experimental procedures and clinical trials
- Electroconvulsive therapy
- Other procedures that the medical staff determines will require a specific explanation to the patient
- Test for HIV (unless a healthcare provider has been exposed to the patient bodily fluids, then consent is not necessary)
- Blood and blood product use
- Any off-label use of medical devices or medications if there is a potential for significant risk

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IV. Who May Provide Consent:

A. Adult Patients

Every competent adult patient may provide consent for his/her own medical/surgical treatment. For purposes of consent, competency may be defined as an ability to understand the nature and consequences of that to which one is asked to consent.

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 it is not an emergency, no one with the legal capacity to consent on behalf of the patient is available, and the attending physician determines that the patient is temporarily incompetent/incapacitated, treatment should be withheld until the patient regains competency/capacity. If the attending physician determines that the patient is permanently incompetent/incapacitated or that it is medically inadvisable to delay treatment until the patient regains competency/capacity, approval should be sought from a member of the patient’s immediate family. While the patient’s family member may not have the legal authority to consent on behalf of the patient, proceeding with the approval of an immediate family member is a generally acceptable practice, particularly when there is a clear medical need for treatment. The attending physician should seek the informed consent of an immediate family member in the following priority, as readily available: (note: state law may also define the order for family member consent)

1. Spouse
2. Adult children
3. Parent
4. Adult siblings
5. Other close relative or significant other

If family members express disagreement regarding whether to proceed and the proposed treatment is life altering, then risk management and/or legal counsel should be consulted before proceeding.

B. 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 (review state laws for the rights of minors seeking medical care):

- Emancipated minors
- Treatment for substance abuse
- Treatment for sexually transmitted diseases
- Contraceptive care
- Prenatal care and treatment
- Abortion
- Mental health care and treatment
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V. 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 someone legally authorized to consent for him/her, 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 consent to any medical/surgical treatment that may be necessary.

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

VI. Refusal to Consent:

A competent adult patient has the right to refuse any medical or surgical procedure (including emergency lifesaving treatment). The patient should be informed of the risks and benefits of treatment and the consequences of the refusal. The patient’s refusal should be noted in 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.

VII. 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 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 procedure or treatment that alters the risks and benefits, discomfort, or side effects originally disclosed to the patient.

VIII. Methods of Consent:

A. Written Consent

A properly signed consent form, obtained prior to treatment, provides evidence of informed consent 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 or her own accord, and witnessed by at least one staff person.

B. Telephone Consent

In certain situations, telephone consent may be required to avoid a delay in treatment. If the authorized representative of the patient can only be reached by telephone, consent by that medium should be obtained. The 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 line.
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IX. Responsibility:

A. Physician Performing Procedure

Physicians are responsible for:

1. Providing the patient with appropriate information in terms/language that he/she understands. Describing the planned procedure will include, but is not limited to, the following:
   - Diagnosis of illness being treated
   - Nature/purpose of the proposed treatment
   - For surgeries, identifying other providers (in addition to the primary surgeon who is obtaining the consent) performing important aspects/significant surgical tasks of the procedure and the specific significant tasks they will perform
   - Risk/consequences of treatment
   - Benefits of the proposed treatment and probability/likelihood of successful outcome
   - Feasible alternatives used
   - Prognosis if no treatment is rendered
   - Giving the patient an opportunity to ask questions and ensuring that all questions have been answered to the patient’s satisfaction

2. Ensuring that all above elements of the informed consent discussed with the patient/legal representative are documented

B. Non-Physician Provider*

Non-physician providers* are responsible for the following:

1. Providing the appropriate forms for surgery, diagnostic and other procedures (invasive and noninvasive) and ensuring that the appropriate consent form is present in the medical record
2. Reviewing the appropriate consent form and/or the supplemental documentation in the medical record - The following information must be included in the record:
   - Patient identity
   - Diagnostic or therapeutic procedure/treatment
   - Name of individual performing procedure
   - Names of other providers (in addition to the primary surgeon who is obtaining the consent) performing important aspects/significant surgical tasks of the procedure and the specific significant tasks they will perform
   - Coverage of the elements of a valid informed consent during the physician provider/patient discussion, including:
     - Diagnosis
     - Nature/purpose of care to be provided
     - Other significantly participating providers
     - Risk/consequences of care
     - Feasible alternatives
     - Potential benefits
     - Prognosis if no treatment is rendered, when applicable
     - Signature by person with capacity to consent
   - Patient/patient representative signature on form or appropriate documentation
3. Being available to witness the patient’s signature - the non-physician provider* is not responsible for securing the consent or ensuring that proper information was given to the patient or patient representative. Nevertheless, immediately prior to having the patient sign the consent form, the non-physician provider* should ask the patient the following questions:
   - Have you read the form?
   - Do you understand the form?
   - Do you have any questions?

4. Contacting the physician provider and department where the treatment/surgery/procedure is to take place, if a signed consent is not present in the medical record and/or the information in item number 2 (above) is not evidenced in the medical record

5. Referring any patient questions regarding the elements of informed consent to the physician provider responsible for obtaining informed consent before the patient signs the consent form

6. Delaying the procedure until the physician provider responsible for the consent/explanation has addressed all questions and the patient has signed the consent form

7. Contacting the appropriate supervisor* or on-call administrator* if the responsible physician provider refuses/fails to respond to the request by the non-physician provider.* The supervisor* or on-call administrator* 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.

X. Miscellaneous

A. 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.

B. Witnesses

Employees who have reached the age of majority may only sign and witness hospital documents. Employees will not become involved in the personal legal affairs of patients.

Surgical consents, permission for autopsy, and various release from responsibility forms will be witnessed by a non-physician provider* or by an employee of the physician office staff who is 18 years of age or older. Nursing students are not to witness legal documents.

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