Integris Group

Risk Management Resource: Informed Consent Policy

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[PLACE ON APPLICABLE HEALTH CARE PROVIDER'S LETTERHEAD]

Informed Consent Policy

We respect the right of patients and their families to participate in healthcare decision making. The physician should obtain and record informed consent before any diagnostic, therapeutic, or invasive procedures and medical interventions or treatments when disclosure of significant medical information would assist a patient in making an informed decision whether to undergo the proposed procedure, intervention, or treatment.

The patient's informed refusal of recommended diagnostic and therapeutic intervention should also be documented. Three key ingredients for informed consent include material risks, anticipated benefits, and feasible alternatives, if any. The physician should also have written policies and procedures to address the written informed consent.

Elements of a thorough informed consent are as follows:

- The name and nature of a proposed treatment or procedure.
- The purpose and anticipated benefits of proposed treatment or procedure.
- The possible material risks and consequences of the treatment or procedure.
- The probability of success.
- The reasonable and feasible alternatives of the proposed treatment or procedure (regardless of costs or extent covered by insurance).
- The risks and benefits of alternatives.
- The risks and benefits of not receiving the proposed treatment or procedure.

During the informed consent process, **first** identify the appropriate decision maker. It is best to sit face-to-face in a private room in the office before the procedure, and at a time when the patient is not distracted or in great pain. Understand that most patients have:

- Only a basic understanding of the medical sciences.
- The right to determine whether to submit to treatment and to decide what will happen to their bodies.
- Dependence upon their physician for the information needed to consent or refuse treatment.

The physician should avoid medical terminology and use language that is easy to understand by the lay person. Also, it is best practice to ask the patient to repeat back in their own words what they believe they are consenting to or refusing. Use of clear, accurate and thorough patient education materials such as videos and/or written materials serves as an extender of the oral conversation with the patient. Provide the patient with an estimate as to how long the treatment or procedure will last, identify any discomforts or side effects associated with the procedure or treatment, and specify how long before the patient can resume normal activities. Informed consent documents should be signed by the provider and patient and

made a part of the patient's medical record. If an interpreter is used, this person's name should be entered on the consent form.

Consent Form

A consent form for each procedure or medical treatment must be prepared to include documentation of the elements referenced above. It also must include the following:

- Name and signature of the patient, or if appropriate, legal guardian
- Name of the hospital/surgical center, if applicable
- Name of all practitioners performing the treatment/procedure
- Date and time consent is signed
- Statement that treatment/procedure was explained to the patient or guardian
- Space to document if the patient has limited English proficiency
- Space for documentation of interpretive services
- Signature of professional person witnessing the consent; and
- Name and signature of person who explained the procedure/treatment to the patient or guardian

To determine a patient or surrogate's decision making capacity, the person must be able to make a particular healthcare decision in a particular clinical context. "Capacity" is a determination that is ordinarily used by a physician in the clinical encounter with any patient or surrogate. In the event that there are concerns about an individual's ability to participate in healthcare decision making, a psychiatry consultation may be helpful as well as consulting with your Risk Manager or legal counsel for guidance. Be sure to document all conversations and pertinent information related to consent.