MedicalMutual
INSURANCE COMPANY OF MAINE

Informed Consent

Informed consent should be obtained for all major therapeutic, diagnostic and invasive procedures/treatments to be completed in the hospital, surgery center, or physician's office. Informed consent is a process whereby the patient is informed of the risks and benefits of a potential procedure/treatment and gives consent to proceed.

It is the physician's responsibility to obtain informed consent from his/her patient. Hospital or office staff may assist in obtaining documentation of the consent, in accordance with the organization's policies and procedures.

Written Policies and Procedures	Yes	No
Do you have a written policy outlining all aspects of the informed consent process?	☐	☐
Does your written policy:		
Indicate which medical procedures or treatments require informed consent?	☐	☐
Indicate who is responsible for obtaining the consent?	☐	☐
Include appropriate methods of documenting the process, including informed consent forms?	☐	☐
Do you periodically review and revise your informed consent policies and procedures?	☐	☐
Other: Specify		
Informed Consent Discussion	**Yes**	**No**
Does your informed consent discussion include:		
The patient's diagnosis and nature of the illness?	☐	☐
The treatment or procedure to be performed and likelihood of success?	☐	☐
The side effects of treatment or procedure?	☐	☐
A summary of risks and benefits? This includes risks an ordinary person would likely want to be informed of.	☐	☐
Alternatives to the treatment or procedure?	☐	☐
Can the patient demonstration understanding of diagnosis, proposed procedure/treatment, risks, benefits and alternatives (ability to "teach back")?	☐	☐
Was the patient given the opportunity to ask questions and have questions answered?	☐	☐
Other: Specify		
Documentation in Patient Medical Record	**Yes**	**No**
Does your documentation include:		
The proposed procedure/treatment and the likelihood of success?	☐	☐
The information you provided to the patient?	☐	☐

The major material risks that were disclosed to the patient?	☐	☐
Disposal and/or use of tissue removed?	☐	☐
The alternatives to the proposed procedure that were discussed with the patient?	☐	☐
The date and time the patient gave consent?	☐	☐
Did you document the patient's understanding of their diagnosis, proposed treatment/procedure, including risks and benefits?	☐	☐
Other: Specify		
Written Informed Consent Form	**Yes**	**No**
Does your written informed consent form include:		
Your facility/practice name?	☐	☐
Patient name and date of birth and/or medical record number?	☐	☐
Diagnosis and nature of the illness?	☐	☐
Treatment and procedure to be performed and the likelihood of success?	☐	☐
Side effects of the treatment or procedure?	☐	☐
Summary of risks and benefits explained to the patient?	☐	☐
Alternatives to the treatment or procedure?	☐	☐
A statement that a physician-in-training or representative from the medical device company may be present at the procedure, as applicable?	☐	☐
A statement that medical photography may be utilized for medical, scientific, or educational purposes, provided the patient's identity is not revealed in the photo or text?	☐	☐
A statement that the patient was given the opportunity to ask and have questions answered?	☐	☐
A statement that the patient demonstrated an understanding of the diagnosis, proposed treatment/procedure, risks, benefits, and alternatives (ability to "teach back")?	☐	☐
The date and time the patient gave consent?	☐	☐
Patient signature?	☐	☐
Physician signature?	☐	☐
Other: Specify		
Notes:		

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