MedPro Group
a Berkshire Hathaway company

Checklist

Informed Consent

Informed consent is a cornerstone of patient engagement and patient-centered care. The process helps patients gain a better understanding of the benefits and risks of proposed procedures and treatments, thus allowing them to make informed decisions about their care.

Physicians, dentists, and other healthcare professionals should engage in thorough informed consent discussions with patients as part of sound clinical practice. Use the checklist below to evaluate your informed consent processes and identify potential areas for improvement.

	Yes	No
Informed Consent Fundamentals		
Are you aware that informed consent is not merely a signed form, but rather a process that involves discussions with patients (and families, if present) about the benefits and risks of procedures or treatments?	☐	☐
Do you understand that informed consent is a nondelegable duty that the treating healthcare provider must perform?	☐	☐
Are staff members who participate in certain aspects of the informed consent process, such as general patient education, properly trained and credentialed?	☐	☐
Are you knowledgeable about the statutes and regulations related to informed consent in the states in which you practice?	☐	☐
If you treat pediatric patients, are you aware of the laws governing informed consent for minors in the states in which you practice?	☐	☐
Are you aware of exceptions to the requirement to engage in informed consent (e.g., during emergency situations)?	☐	☐
Do your informed consent forms adhere to applicable federal and state statutes and regulations concerning informed consent?	☐	☐

	Yes	No
Informed Consent Policies and Processes		
Does your healthcare organization have a policy for managing situations that might complicate the informed consent process, such as treating a patient who has cognitive disabilities or treating a pediatric patient whose parents do not agree on treatment?	☐	☐
Does the type of procedure or treatment and its complexity help determine the thoroughness and level of detail presented during the informed consent process?	☐	☐
Do you modify the informed consent process based on each patient's specific condition and circumstances rather than using a one-size-fits-all approach?	☐	☐
As part of the informed consent process, do you consider patients': • Current understanding of their conditions? • Overall capacity to understand the information provided, including any language or health literacy barriers? • Cultural, religious, socioeconomic, or ideological circumstances, which might affect their decision-making process?	☐ ☐ ☐	☐ ☐ ☐
At a minimum, does the informed consent process and form (if applicable) include basic elements, such as the patient's name, the procedure name, a description of the procedure, the benefits/risks of the procedure, alternative treatment options, the patient's signature acknowledging understanding, and a witness signature?	☐	☐
Do you follow a process similar to informed consent when a patient refuses treatment (i.e., discussing the benefits/risks of not pursuing treatment and alternative options)?	☐	☐
Are thorough and valid informed consent processes and forms used for patients who are participating in research or investigational procedures/treatments?	☐	☐
Patient Comprehension		
Do you use lay language and clear descriptions of treatments and procedures when conducting the informed consent process?	☐	☐
Do you avoid medical jargon and try to explain complex medical concepts in ways that aid patient comprehension (e.g., using visual aids)?	☐	☐

	Yes	No
Patient Comprehension (continued)		
Do written materials, including forms and patient educational pieces, adhere to the principles of plain language?	☐	☐
Are interpreters and auxiliary aids used as part of the informed consent process for patients who have limited English proficiency or disabilities such as hearing impairment?	☐	☐
Is patient comprehension of the informed consent process assessed through methods such as the teach-back technique?	☐	☐
Are patients given opportunities to ask questions and clarify information during and after the informed consent process?	☐	☐
Informed Consent Documentation		
Does your organization have a protocol for consistently documenting informed consent (or informed refusal) and patient education in patients' health records?	☐	☐
Do you document the informed consent or informed refusal process in each patient's record, regardless of the complexity of the procedure?	☐	☐
At a minimum, does informed consent/informed refusal documentation include:		
• Information about the patient's diagnosis?	☐	☐
• The procedure or treatment that you are recommending to the patient and its purpose?	☐	☐
• The benefits and risks of the procedure or treatment as discussed with the patient?	☐	☐
• The patient's acceptance or refusal of the treatment plan (including reason for refusal, if applicable)?	☐	☐
• Information about any patient education (written or verbal) provided?	☐	☐
Are signed informed consent forms included in patient records?	☐	☐

Resources

More information and resources about informed consent and informed refusal can be found in MedPro Group's *Risk Management Strategies for Informed Consent* guideline and *Risk Resources: Informed Consent*.