Quick Check:
INFORMED CONSENT PROCESS

The Doctors Company
TDC GROUP

Completing this checklist can help you improve your informed consent process and documentation. For any "No" response, consider updating your process.

	Yes	No	Notes
Informed Consent Discussions and Documentation			
1. The practice has established a written plan, consistently followed by staff, that provides patients with an informed consent discussion for invasive procedures and/or treatment regimens associated with risk. This applies to medical, surgical, or dental treatment and to high-risk medications.			
2. The practice acknowledges that true informed consent is not a signature on a form or a one-time event. It is a process of managing a patient's expectations. Discussions with patients regarding complex interventions take place in advance and often more than one time in order to give them opportunities to consider their choices.			
3. The practice provides education to enhance patients' ability to make informed decisions about their care.			
4. The practice documents in the patient record all education provided to the patient.			
5. The practice maintains an administrative file with an archive of the supplemental education materials and resources it has distributed to patients each year. (This archive may be needed for defense purposes in the event of a claim.)			
6. The practice acknowledges that the practitioner must provide the informed consent discussion and that this responsibility cannot be delegated to a staff member.			
7. In discussions with patients, the practitioner explains diagnoses, treatment alternatives, expected outcomes, and potential risks, while acknowledging the patient's rights and remaining responsive to them. The recovery process is discussed and described realistically. Patients are encouraged to ask questions.			
8. Discussions also include shared decision-making responsibility, shifting from the practitioner alone to mutual responsibility by both the practitioner and the patient.			
9. Informed consent discussions are documented (along with the consent form) in the progress notes of the patient record.			
10. The practice is aware of the informed consent documentation requirements in its jurisdiction.			
11. Clinical and technical terminology is avoided in informed consent discussions with patients. Clinical words are explained and simple drawings and/or models are used to enhance patient understanding.			
12. Educational materials and consent form documents are provided at a level no higher than the eighth grade.			
13. Health literacy "universal precautions" are used with every patient. This means that communication with every patient is simplified and made easy to understand.			

	Yes	No	Notes
Informed Consent Form			
14. Whenever possible, consent forms are specific to the procedure.			
15. Consent forms are translated into the most common non-English languages encountered in the practice.			
16. Interpreters are used for informed consent discussions when necessary, with interpreter identity and qualifications documented.			
17. The consent form is completed and notes are also made in the progress notes to document information regarding patient engagement, concerns, and questions.			
18. The consent form includes the patient's name, healthcare practitioner's name, diagnosis, proposed treatment plan, alternatives, potential risks, complications, and benefits.			
19. The consent form is signed and dated by the patient or the patient's legal guardian or representative. (Ideally, the healthcare practitioner also signs the consent form.)			
20. The consent form attests that the patient understands the information provided.			
21. The consent form also attests that the practitioner has answered all questions completely and believes that the patient fully understands the information.			
22. The practice acknowledges that any member of the healthcare team may sign the consent form as a witness, but only the practitioner may obtain consent or verify the patient's competency to give consent.			
23. If the patient is incompetent or unable to give consent, the practitioner obtains consent from the patient's authorized representative, except in an emergency.			
24. For patients who refuse recommended care, an informed refusal discussion takes place and is documented, ideally with an informed refusal form signed by the patient.			
25. The practice is aware that The Doctors Company provides customizable sample consent forms that can be adapted to specific procedures.			

The Doctors Company Resources

- Sample Informed Consent Forms at **thedoctors.com/sampleconsentforms**
- Article: "Informed Consent: Substance and Signature" at **thedoctors.com/substanceandsignature**
- Article and Sample Form: "Informed Refusal" at **thedoctors.com/informedrefusal**
- Education: *Risk Management Fundamentals for the Practice Manager* at **thedoctors.com/practicemanager**

Additional Resources

- AHRQ Health Literacy Universal Precautions Toolkit, 2nd Edition, at **ahrq.gov/health-literacy/improve/precautions/toolkit.html**
- John Hopkins Medicine: Informed Consent Guidance—How to Prepare a Readable Consent Form, at **hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/informed_consent_ii.html**

For additional guidance, contact the Department of Patient Safety and Risk Management at **800.421.2368** or by email at **patientsafety@thedoctors.com**.