

Informed Consent Policy Worksheet

Policy Component	Does your policy:	What improvements are needed, if any?
1. Statement of purpose	<p>Have a statement of purpose?</p> <p>Is your statement of purpose in sync with your hospital's mission statement?</p> <p>Will it resonate with your hospital's culture?</p> <p>Is the language unambiguous?</p> <p>Is the goal clear without getting bogged down in detail?</p>	
2. General policy	<p>Outline the key principles of informed consent?</p> <p>Does it give an overview of what the policy covers?</p> <p>Clearly list patients' rights?</p>	
3. Who is responsible	<p>Clearly specify:</p> <ul style="list-style-type: none"> Who is responsible for obtaining informed consent? What aspects of the informed consent process can be delegated? To whom? What role each team member plays? 	
4. Explicit consent	<p>Comprehensively list of what tests, treatments, and procedures require explicit consent?</p> <p>Are the definitions clear?</p>	
5. Timing	<p>Include information regarding the timing of the informed consent discussion?</p>	

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6. Content of an informed consent discussion	<p>Include information regarding the content of an informed consent discussion?</p> <p>Specify that the discussion should include:</p> <ul style="list-style-type: none"> • Patient's condition and need for tests/ treatments/ procedures? • Description of all feasible options (i.e., possible tests/treatments/ procedures)? • Who will perform and their experience? • Probable benefits and harms <ul style="list-style-type: none"> ○ Anticipated results ○ Temporary discomfort, disability or disfigurement ○ Probable complications ○ Any permanent results • Risks, including remote but severe risks? • Option of getting no treatment, and its benefits, harms, and risks? • Any plans the care team has to film, photograph, or record? • Encourages questions? • Teach-Back to check understanding? 	
7. Documentation of consent	<p>Clearly state:</p> <ul style="list-style-type: none"> • Which procedures are covered by blanket consent? • When a signature is required? • What documentation is needed for verbal consent and by whom? 	

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8. Verification of consent	Specify who is accountable for verifying consent discussions that have taken place outside the hospital?	
9. Exceptions to informed consent	<p>Clearly enumerate exceptions, such as treatment that is legally-mandated/ court-ordered or a patient asks not to be informed?</p> <p>Does it define what constitutes an emergency?</p> <p>Does it specify when a patient is considered incapacitated?</p>	
10. Informed consent for minors	<p>Clearly define:</p> <ul style="list-style-type: none"> • Who is a mature minor? • What services minors can consent to? • When clinicians should seek assent by minors? 	
11. Clear communication	<p>Include information regarding clear communication to ensure understanding?</p> <p>Foster a culture of clear communication by highlighting the importance of:</p> <ul style="list-style-type: none"> • Using plain language, clear and simple forms, high-quality decision aids, and graphics and other educational materials? • Always using teach-back to verify comprehension? • Accommodating patients' communication needs with professionally translated forms, language assistance, visual aids, or reading assistance? 	

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12. Compliance	<p>Comply with:</p> <ul style="list-style-type: none"> Federal, State and local laws? Regulations (e.g. CMS rules)? Accreditation standards? 	
13. Enforcement	<p>Include information regarding enforcement?</p> <p>Clearly state who to call if someone observes a violation of the policy?</p>	
14. Periodic Policy Review	<p>Specify:</p> <ul style="list-style-type: none"> A review schedule? Who should review the policy? How often it should be reviewed? 	
15. Dissemination	<p>How does your hospital inform patients and clinicians about its informed consent policy?</p> <p>What other channels could be used to better disseminate this information? (e.g.: online, brochures, information sheets, posters, trainings, patient/family-centered networks?)</p>	