Informed Consent Systems Worksheet

Systems Component	Does your hospital have:	What improvements are needed, if any?
Supportive System #1. Library of plain-language informed consent forms	A single centralized library of standardized informed consent forms? Does it include forms for **all** tests, procedures, and treatments that require a written informed consent? Is each form listing the appropriate benefits, harms, and risks with no unnecessary information? Has each form been checked for: • Comprehensiveness? • Accuracy? • Incorporation of latest evidence? • Adherence to health literacy principles? • Understandability? Have forms been professionally translated into languages commonly spoken by your patients? Have forms been tested with a sample of diverse patients including patients who have a vision impairment? Is someone charged with maintaining the library? How are the forms distributed or accessed by clinicians? Is there a process for approving new forms and periodically reviewing and updating approved forms? How are staff notified when a form is changed?	
Supportive System #2. Library of high-quality decision aids and patient education materials	A single centralized library of high-quality decision aids and patient education materials?	

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Systems Component	Does your hospital have:	What improvements are needed, if any?

	Is the library comprehensive (i.e., include materials for all common tests, treatments, and procedures)?
	
	Has each material in the library been assessed for quality, verifying that it:
	• Comes from a reliable source
	• Is complete
	   o All feasible options
	   o Benefits, harms, and risks
	   o Option of no treatment
	• Is based on up-to-date scientific evidence
	• Is unbiased
	• Is understandable
	   o Health literacy strategies
	   o Multiple languages
	   o Moderately paced and distinct audio
	• Clarifies patient's goals and values
	
	Have forms been tested with a sample of diverse patients including patients who have a vision impairment?
	
	Is someone charged with identifying materials and maintaining the library?
	
	How are the forms distributed or accessed by clinicians?
	
	Is there a process for approving new materials and periodically reviewing and updating them?
	
	How are staff encouraged to use the materials?	

Supportive System #3. Removing Communication Barriers	Have a: • Systematic and accurate way to identify patients' preferred language?	

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Informed Consent Systems Worksheet

Systems Component	Does your hospital have:	What improvements are needed, if any?
	• System to verify language skills of bilingual staff? • System to access qualified medical interpreters 24/7, including sign languages interpreters? Is someone charged with planning for and implementing language assistance? Is the necessary communication equipment acquired and maintained (e.g., dual handset phones, video interpreting equipment, devices for sound amplification and magnifying readers)? Are staff trained on when and how to access interpreters and other communication supports?	
Supportive System #4. Clear, efficient workflows for informed consent	Have clear, efficient workflows for informed consent? A process that meets the letter **and** the spirit of your hospital's informed consent policy? Is your process easy for patients? Does it take into account the diversity of patients? Is your process efficient? Have roles of each staff member been unambiguously assigned?	

Informed Consent Systems Worksheet

Systems Component	Does your hospital have:	What improvements are needed, if any?
Supportive System #5. Staff Training	Training for all staff on informed consent principles and hospital policy? Do you provide training on strategies for clear communication, such as: • Preparation for the informed consent discussion • Health literacy universal precautions • Language preference identification and when to use interpreters • Teach back Is there training that addresses strategies for presenting choices, including: • Informed consent principles and hospital policy? • Strategies for clear communication? • How to offer choices and explain benefits, harms and risks of all options? • Engaging patients and family members? • Eliciting goals and values? • Using decision aids and patient education materials? Are all responsible staff members training on how to properly document informed consent?	