

Attachment C- Baseline and Final Assessment of Hospital Informed Consent Process

BASELINE ASSESSMENT

Pre-Interview Form

The following are structured questions the hospital liaison and unit leads will be asked to complete before the baseline assessment interview.

Hospital: _____ Unit: _____

Respondent: _____ Date: _____

1. For tests/treatments/procedures that require informed consent, how frequently do clinicians in your unit do the following when obtaining informed consent?

Check "DK" (Don't Know) if you don't know what clinicians do in your unit.

	Never	Sometimes	Usually	Always	DK
a) Assess patients' decision-making capacity					
b) Allocate ample time in private space					
c) Use health literacy universal precautions					
d) Call for qualified interpreters when conducting a consent discussion with a patient who speaks a different language					
e) Use teach-back					
f) Offer choices, including the option of doing nothing					
g) Engage patients, family, and friends in the consent discussion					
h) Elicit goals and values					
i) Encourage questions					
j) Use high-quality structured patient decision aids (e.g., tool to help a patient understand the benefits, harms, and risks of a procedure and make a decision)					
k) Neutrally explain the benefits,					

harms, and risks of all options					
l) Use teach-back techniques to check patient understanding					
m) Better document the informed consent discussion					
n) Ask patients to confirm consent immediately before test, treatment, or procedure when consent has been given in advance					

2. To what extent do you think clinicians obtaining consent in your hospital/unit agree or disagree with the following statements:

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
a) Clinicians should encourage patients to talk about their values when deciding whether to consent to a test, treatment, or procedure					
b) Clinicians are in a better position than patients to decide which tests, treatments, or procedures patients need					
c) Clinicians should not present alternatives that are demonstrably less effective					
d) Refusing a life-saving treatment or procedure demonstrates that the patient is not capable of making a sound decision					
e) Clinicians are responsible for ensuring that patients understand all their options before making a decision					
f) Getting the patient's signature on a consent form is the most critical part of the informed					

	consent process					
g)	Lack of patient understanding of benefits, harms, and risks of treatments is a serious patient safety problem					
h)	The informed consent process is worth the time it takes					
i)	The chief purpose of informed consent processes is to comply with regulations and be protected from lawsuits					

Public reporting burden for this collection of information is estimated to average 60 minutes per response, the estimated time required to complete the pre-interview form and interview. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX) AHRQ, 540 Gaither Road, Room # 5036, Rockville, MD 20850.

Interview Protocol

The following are semi-structured questions to be asked of the hospital liaison and unit leads during a telephone interview.

Hospital: _____ Interviewer: _____

Unit: _____ Respondent: _____

Date: _____ Module(s) Completed: _____

Obtained signed consent form: Y/N Interviewer Initials: _____

Permission to record: Y/N Interviewer initials: _____

Role in Informed Consent

1. What are your roles and responsibilities in informed consent for tests/treatments/procedures in your hospital/your unit?

Informed Consent Policies and Process

2. What is your hospital's informed consent policy? [Interviewer: If there's a written policy, obtain a copy.]
 - a. Does it vary by unit? If so, how?
 - b. How closely would you say staff members follow the hospital's policy?
3. Describe the informed consent process workflow in your hospital/unit in terms of what happens, when, and by whom?
4. Which clinicians are responsible for obtaining informed consent, that is, having the informed consent discussion with patients, in your hospital/unit (e.g., MDs, NPs, PAs, RNs, others)?
 - a. Does anyone other than the clinician performing the test, treatment, or procedure ever obtain informed consent (e.g., residents for attending physicians, nurses for doctors)?
5. Who else besides the clinician obtaining consent has responsibility for how informed consent happens in your hospital/unit (e.g., does the risk manager or quality officer have a responsibility with regard to informed consent)?

Public reporting burden for this collection of information is estimated to average 60 minutes per response, the estimated time required to complete the pre-interview form and interview. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX) AHRQ, 540 Gaither Road, Room # 5036, Rockville, MD 20850.

6. Which aspects of informed consent are documented, how and by whom?
 - a. A signed informed consent form?
 - b. Documentation of an informed consent discussion?
 - c. Confirmation of consent provided by patient?

Informed Consent Effectiveness

7. Do you think most clinicians obtaining consent in your hospital/unit treat the informed consent process as merely getting a signature on a form, or do they tend to really make sure patients understand that they have choices and what those choices are? Please explain.
8. On a scale from 1 to 10, where 1 is the worst and 10 is the best, how well does your hospital/unit ensure patients are making an informed choice? Please explain your score.

Informed Consent Quality and Issues

9. Has your hospital/unit had any accreditation, legal, or safety accreditation issues related to informed consent in the past 5 years? If so, please describe.
10. Has informed consent come up as an opportunity for improvement in your hospital/unit from leadership, a quality officer, patient and family advisory council, or others in the past 5 years? Please explain.
11. Has your hospital/unit made or attempted improvements or changes in your informed consent processes in the past 5 years? If so, what were they? Were they considered successful? Why?
12. What do you think your hospital/unit is doing well in your informed consent practices?
13. What do you think your hospital/unit could do better in your informed consent practices?

Role in Implementation

14. What will your role be in improving informed consent in your hospital/unit using the training modules and tools?

Implementation Climate [Interviewer: refer to pre-interview responses as appropriate.]

15. In general, do you think your hospital/unit staff and leadership perceive there is a need to improve your informed consent practices?
16. How well do you think improving informed consent practices aligns with your hospital's/unit's norms or values?

17. How did your hospital/unit determine that you wanted to implement the training modules?
 - a) Has your hospital/unit undertaken efforts to systematically assess the state of informed consent in your hospital/unit? Tell me about it.
 - b) What other measures or tools did you use?
 - c) How did you decide which units would implement the training modules/strategies?
18. Is improving informed consent practices a priority for your hospital/unit? How so/Why not?
19. In what ways is your leadership supporting improvements in informed consent in your hospital/unit? In what way is this a change from the past?
20. What resources are being dedicated to improving informed consent?
21. What are your hospital's/unit's goals for implementing the training modules/specific tools/strategies?

PROBES:

- To improve patient satisfaction.
 - To improve patient understanding and safety.
 - To live up to the principles of informed consent.
 - To improve staff morale.
 - To make obtaining informed consent more efficient.
 - To bring our hospital/unit into compliance with regulations.
 - To reduce the threat of lawsuits.
22. What do you think the greatest challenges will be to achieving these goals?
 23. What do you think will help your hospital/unit to achieve these goals?
 24. What motivated you to champion/lead these changes in your hospital?
 25. What are the motivations for health care professionals to make changes to improve informed consent?
 26. What information will staff be given at the outset and throughout the initiative about the changes being made (e.g., goals of the changes, periodic feedback, and learning)?

Background Information

27. How long have you worked in this hospital?
28. How long have you worked in your current hospital work area/unit?

29. What is your staff position in this hospital?

PROBES: MD, RN, PA, NP, LVN/LPN, Aide, Attending MD, hospitalist, resident, fellow

30. How long have you worked in your current specialty or profession?

Characteristics of Pilot Testing Units

31. The following information will be collected from the Hospital Liaison and/or the Unit Lead at baseline, including:

- a. Unit name and description (e.g., specific services or surgeries provided in unit),
- b. Bed size
- c. Staff (number, type, roles).

FINAL ASSESSMENT

Pre-Interview Form

The following are structured questions the hospital liaisons and unit leads will be asked to complete before the final assessment interview.

Hospital: _____ Unit: _____

Respondent: _____ Date: _____

1. For tests/treatments/procedures that require informed consent, how frequently do clinicians in your unit do the following when obtaining informed consent?

Check "DK" (Don't Know) if you don't know what clinicians do in your unit.

	Never	Sometimes	Usually	Always	DK
a) Assess patients' decision-making capacity					
b) Allocate ample time in private space					
c) Use health literacy universal precautions					
d) Call for qualified interpreters when conducting a consent discussion with a patient who speaks a different language					
e) Use teach-back					
f) Offer choices, including the option of doing nothing					
g) Engage patients, family, and friends in the consent discussion					
h) Elicit goals and values					
i) Encourage questions					
j) Use high-quality structured patient decision aids (e.g., tool to help a patient understand the benefits, harms, and risks of a procedure and make a decision)					
k) Neutrally explain the benefits, harms, and risks of all options					
l) Use teach-back techniques to check patient understanding					
m) Better document the informed consent discussion					
n) Ask patients to confirm consent immediately before test, treatment,					

or procedure when consent has been given in advance					
---	--	--	--	--	--

2. To what extent do you think clinicians obtaining consent in your hospital/unit agree or disagree with the following statements:

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
a) Clinicians should encourage patients to talk about their values when deciding whether to consent to a test, treatment, or procedure					
b) Clinicians are in a better position than patients to decide which tests, treatments, or procedures patients need					
c) Clinicians should not present alternatives that are demonstrably less effective					
d) Refusing a life-saving treatment or procedure demonstrates that the patient is not capable of making a sound decision					
e) Clinicians are responsible for ensuring that patients understand all their options before making a decision					
f) Getting the patient's signature on a consent form is the most critical part of the informed consent process					
g) Lack of patient understanding of benefits, harms, and risks of treatments is a serious patient safety problem					
h) The informed consent process is worth the time it takes					

i) The chief purpose of informed consent processes is to comply with regulations and be protected from lawsuits					
---	--	--	--	--	--

Interview Protocol

The following are semi-structured questions to be asked of the hospital liaison and unit leads during a telephone interview.

Hospital: _____ Interviewer: _____

Unit: _____ Respondent: _____

Date: _____ Module(s) Completed: _____

Obtained signed consent form: Y/N Interviewer Initials: _____

Permission to record: Y/N Interviewer initials: _____

Informed Consent Policies and Process

1. Have there been any changes since we last spoke in your hospital's/unit's informed consent policy? If so, what?
2. Have there been any changes since we last spoke in the informed consent process workflow in your hospital/unit in terms of what happens, when, and by whom?
3. Have there been any changes since we last spoke in terms of staff role and responsibilities in informed consent in your hospital/unit?
4. Have there been any changes since we last spoke in terms of others' responsibility for how informed consent happens in your hospital/unit (e.g., does the risk manager or quality officer have a responsibility with regard to informed consent)?
5. Have there been any changes since we last spoke with regard to which aspects of informed consent are documented, how and by whom?

Public reporting burden for this collection of information is estimated to average 60 minutes per response, the estimated time required to complete the pre-interview form and interview. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX) AHRQ, 540 Gaither Road, Room # 5036, Rockville, MD 20850.

Public reporting burden for this collection of information is estimated to average 60 minutes per response, the estimated time required to complete the pre-interview form and interview. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX) AHRQ, 540 Gaither Road, Room # 5036, Rockville, MD 20850.

6. Have there been any other changes resulting from the informed consent improvement initiative since we last spoke?

Informed Consent Effectiveness

7. Do you think most clinicians obtaining consent in your hospital/unit treat the informed consent process as merely getting a signature on a form, or do they tend to really make sure patients understand that they have choices and what those choices are? Please explain.
8. On a scale from 1 to 10, where 1 is the worst and 10 is the best, how well does your hospital/unit ensure patients are making an informed choice?
 - a. Last time you were interviewed your score was [enter score]. To what do you attribute the difference?

Informed Consent Quality and Issues

9. Has your hospital/unit had any accreditation, legal, or safety accreditation issues related to informed consent since this initiative began? If so, please describe.

Results

10. What do you think your hospital/unit is doing better in your informed consent practices since this initiative began?
 - a. To what do you attribute these improvements?
11. Have informed consent practices gotten worse in any respect since this initiative began?
 - a. To what do you attribute this deterioration?
12. What do you think your hospital/unit could do better in your informed consent practices, even after this initiative?
13. Did your hospital/unit achieve the goals it set out before the initiative, specifically [insert goals from Baseline]?
14. What helped your hospital/unit achieve those goals?
15. What were the greatest challenges to achieving those goals?
16. What could have helped your hospital/unit to achieve goals that it didn't achieve?

Conclusion

17. Do you have any advice on how we might improve the training modules?
18. What advice do you have to give to other hospitals/units who want to use these training modules to improve their informed consent processes?
19. Is there anything else you think would be helpful for us to know about your experience with the training modules and implementing changes?