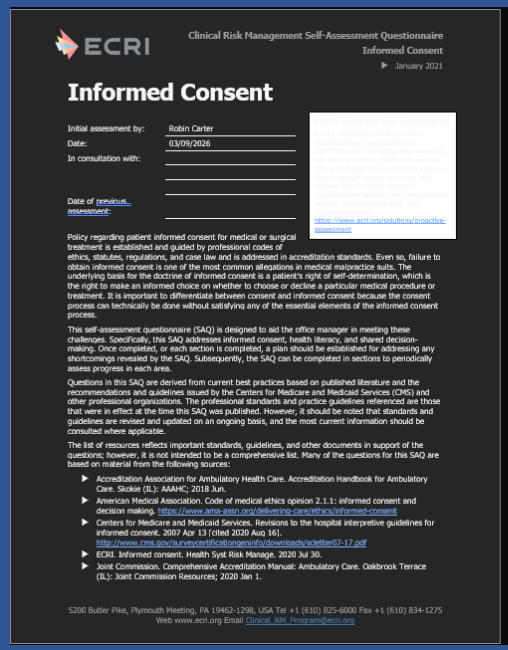
2026 Q1 Quarterly Risk Assessment

SOUTHERN NEVADA Community HEALTH CENTER

2026 Q1 Quarterly Risk Assessment

- FTCA requires one risk assessment to be completed each quarter. 2 of the 4 risk assessments must cover a high-risk area.
- The one required risk assessment for Q1 is complete, making the requirement at 100% compliance through Q1.
- The tool used for the Q1 Risk Assessment is called the ECRI Clinical Risk Management Self-Assessment Questionnaire - Informed Consent
- Criteria Audited
  - Conducted by medical director on 3/9/2026
  - 26/43 compliant (60.5%)
  - Action Plan to correct other 17 criteria done and under way.
    - 12/17 will be corrected with a policy/form update.
- Goal is to have 75% or fewer action items open from risk assessments


ECRI
Clinical Risk Management Self-Assessment Questionnaire
Informed Consent
January 2021

Informed Consent

Initial assessment by: Robin Carter
Date: 03/09/2026
In consultation with:
Date of previous assessment:

Policy regarding patient informed consent for medical or surgical treatment is established and guided by professional codes of ethics, statutes, regulations, and case law and is addressed in accreditation standards. Even so, failure to obtain informed consent is one of the most common allegations in medical malpractice suits. The underlying basis for the doctrine of informed consent is a patient's right of self-determination, which is the right to make an informed choice on whether to choose or decline a particular medical procedure or treatment. It is important to differentiate between consent and informed consent because the consent process can technically be done without satisfying any of the essential elements of the informed consent process.

This self-assessment questionnaire (SAQ) is designed to aid the office manager in meeting these challenges. Specifically, this SAQ addresses informed consent, health literacy, and shared decision-making. Once completed, or each section is completed, a plan should be established for addressing any shortcomings revealed by the SAQ. Subsequently, the SAQ can be completed in sections to periodically assess progress in each area.

Questions in this SAQ are derived from current best practices based on published literature and the recommendations and guidelines issued by the Centers for Medicare and Medicaid Services (CMS) and other professional organizations. The professional standards and practice guidelines referenced are those that were in effect at the time this SAQ was published. However, it should be noted that standards and guidelines are revised and updated on an ongoing basis, and the most current information should be consulted where applicable.

The list of resources reflects important standards, guidelines, and other documents in support of the questions; however, it is not intended to be a comprehensive list. Many of the questions for this SAQ are based on material from the following sources:

- Accreditation Association for Ambulatory Health Care. Accreditation Handbook for Ambulatory Care. Skokie (IL): AAAHC; 2018 Jun.
- American Medical Association. Code of medical ethics opinion 2.1.1: informed consent and decision making. https://www.ama-assn.org/delivering-care/ethics/informed-consent
- Centers for Medicare and Medicaid Services. Revisions to the hospital interpretive guidelines for informed consent. 2007 Apr 13 [cited 2020 Aug 16]. http://www.cms.gov/surveycertificationgeninfo/downloads/sletter07-17.pdf
- ECRI. Informed consent. Health Syst Risk Manage. 2020 Jul 30.
- Joint Commission. Comprehensive Accreditation Manual: Ambulatory Care. Oakbrook Terrace (IL): Joint Commission Resources; 2020 Jan 1.

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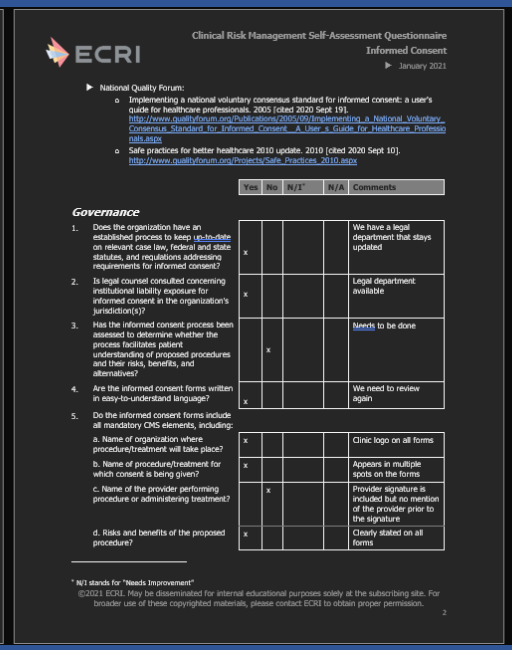
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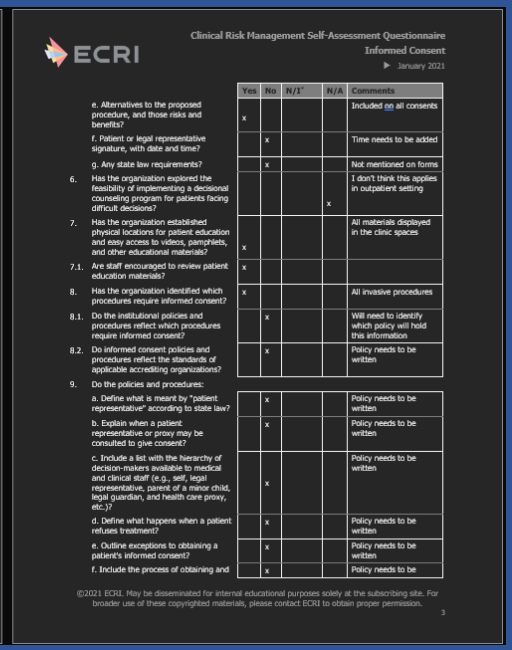
- National Quality Forum:
  - Implementing a national voluntary consensus standard for informed consent: a user's guide for healthcare professionals. 2005 [cited 2020 Sept 19]. http://www.qualityforum.org/Publications/2005/09/Implementing_a_National_Voluntary_Consensus_Standard_for_Informed_Consent__A_User_s_Guide_for_Healthcare_Professionals.aspx
  - Safe practices for better healthcare 2010 update. 2010 [cited 2020 Sept 10]. http://www.qualityforum.org/Projects/Safe_Practices_2010.aspx

		Yes	No	N/1*	N/A	Comments
Governance						
1.	Does the organization have an established process to keep up-to-date on relevant case law, federal and state statutes, and regulations addressing requirements for informed consent?	x				We have a legal department that stays updated
2.	Is legal counsel consulted concerning institutional liability exposure for informed consent in the organization's jurisdiction(s)?	x				Legal department available
3.	Has the informed consent process been assessed to determine whether the process facilitates patient understanding of proposed procedures and their risks, benefits, and alternatives?		x			Needs to be done
4.	Are the informed consent forms written in easy-to-understand language?	x				We need to review again
5.	Do the informed consent forms include all mandatory CMS elements, including:					
	a. Name of organization where procedure/treatment will take place?	x				Clinic logo on all forms
	b. Name of procedure/treatment for which consent is being given?	x				Appears in multiple spots on the forms
	c. Name of the provider performing procedure or administering treatment?		x			Provider signature is included but no mention of the provider prior to the signature
	d. Risks and benefits of the proposed procedure?	x				Clearly stated on all forms

* N/1 stands for "Needs Improvement"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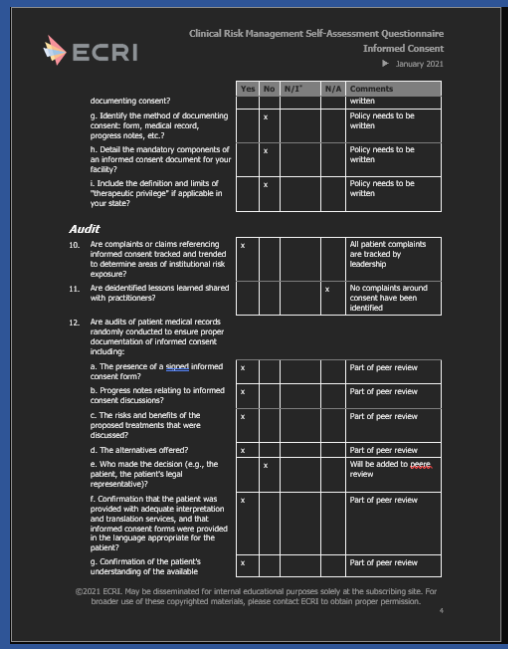
		Yes	No	N/1*	N/A	Comments
	e. Alternatives to the proposed procedure, and those risks and benefits?	x				Included on all consents
	f. Patient or legal representative signature, with date and time?		x			Time needs to be added
	g. Any state law requirements?		x			Not mentioned on forms
6.	Has the organization explored the feasibility of implementing a decisional counseling program for patients facing difficult decisions?				x	I don't think this applies in outpatient setting
7.	Has the organization established physical locations for patient education and easy access to videos, pamphlets, and other educational materials?	x				All materials displayed in the clinic spaces
7.1.	Are staff encouraged to review patient education materials?	x				
8.	Has the organization identified which procedures require informed consent?	x				All invasive procedures
8.1.	Do the institutional policies and procedures reflect which procedures require informed consent?		x			Will need to identify which policy will hold this information
8.2.	Do informed consent policies and procedures reflect the standards of applicable accrediting organizations?		x			Policy needs to be written
9.	Do the policies and procedures:					
	a. Define what is meant by "patient representative" according to state law?		x			Policy needs to be written
	b. Explain when a patient representative or proxy may be consulted to give consent?		x			Policy needs to be written
	c. Include a list with the hierarchy of decision-makers available to medical and clinical staff (e.g., self, legal representative, parent of a minor child, legal guardian, and health care proxy, etc.)?		x			Policy needs to be written
	d. Define what happens when a patient refuses treatment?		x			Policy needs to be written
	e. Outline exceptions to obtaining a patient's informed consent?		x			Policy needs to be written
	f. Include the process of obtaining and		x			Policy needs to be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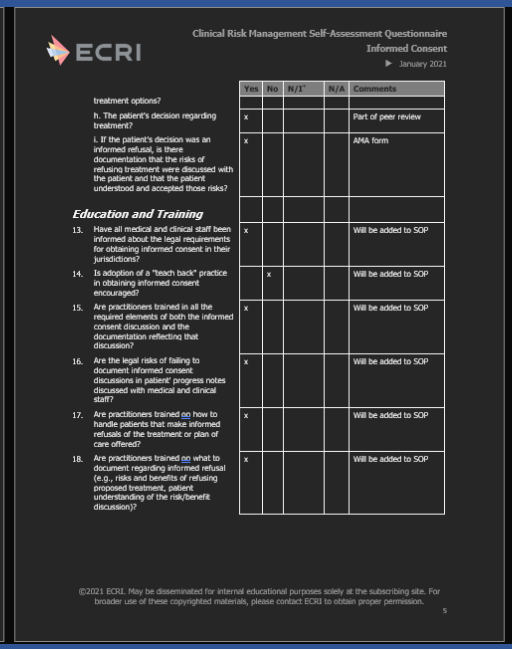
		Yes	No	N/1*	N/A	Comments
	documenting consent?					written
	g. Identify the method of documenting consent: form, medical record, progress notes, etc.?		x			Policy needs to be written
	h. Detail the mandatory components of an informed consent document for your facility?		x			Policy needs to be written
	i. Include the definition and limits of "therapeutic privilege" if applicable in your state?		x			Policy needs to be written
Audit						
10.	Are complaints or claims referencing informed consent tracked and trended to determine areas of institutional risk exposure?	x				All patient complaints are tracked by leadership
11.	Are deidentified lessons learned shared with practitioners?				x	No complaints around consent have been identified
12.	Are audits of patient medical records randomly conducted to ensure proper documentation of informed consent including:					
	a. The presence of a signed informed consent form?	x				Part of peer review
	b. Progress notes relating to informed consent discussions?	x				Part of peer review
	c. The risks and benefits of the proposed treatments that were discussed?	x				Part of peer review
	d. The alternatives offered?	x				Part of peer review
	e. Who made the decision (e.g., the patient, the patient's legal representative)?		x			Will be added to peers review
	f. Confirmation that the patient was provided with adequate interpretation and translation services, and that informed consent forms were provided in the language appropriate for the patient?	x				Part of peer review
	g. Confirmation of the patient's understanding of the available	x				Part of peer review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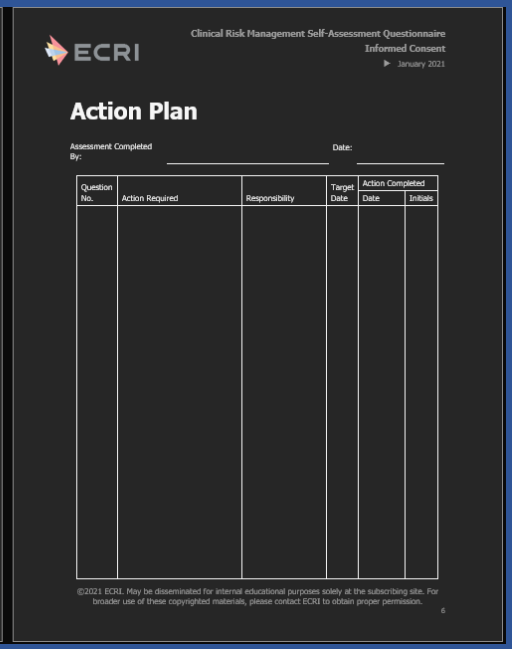
		Yes	No	N/1*	N/A	Comments
	treatment options?					
	h. The patient's decision regarding treatment?	x				Part of peer review
	i. If the patient's decision was an informed refusal, is there documentation that the risks of refusing treatment were discussed with the patient and that the patient understood and accepted those risks?	x				AMA form
Education and Training						
13.	Have all medical and clinical staff been informed about the legal requirements for obtaining informed consent in their jurisdictions?	x				Will be added to SOP
14.	Is adoption of a "teach back" practice in obtaining informed consent encouraged?		x			Will be added to SOP
15.	Are practitioners trained in all the required elements of both the informed consent discussion and the documentation reflecting that discussion?	x				Will be added to SOP
16.	Are the legal risks of failing to document informed consent discussions in patient' progress notes discussed with medical and clinical staff?	x				Will be added to SOP
17.	Are practitioners trained on how to handle patients that make informed refusals of the treatment or plan of care offered?	x				Will be added to SOP
18.	Are practitioners trained on what to document regarding informed refusal (e.g., risks and benefits of refusing proposed treatment, patient understanding of the risk/benefit discussion)?	x				Will be added to SOP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Action Plan

Assessment Completed By: Date:

Question No.	Action Required	Responsibility	Target Date	Action Completed	
				Date	Initials

SOUTHERN NEVADA Community HEALTH CENTER

2026 Q1 Quarterly Risk Assessment Findings

17 Findings

CY26 ECRI Self-Assessment Tool for Informed Consent - Findings and Action Plan

Assessment conducted by: **Dr. Robin Carter, DO, Medical Director**

Q1 Assessment Completed on: **3/9/2026**

Overall Score: **26/43 or 60.5%**

Findings/areas of highest risk identified:

1. **Governance –**
    a. # 3: Has the informed consent process been assessed to determine whether the process facilitates patient understanding of proposed procedures and their risks, benefits, and alternatives?
        i. Assessment Notes: No - This needs to be done
    b. #5c, 5f, 5g: Do the informed consent forms include all mandatory CMS elements, including: Name of the provider performing procedure or administering treatment? Patient or legal representative signature, with date and time? Any State law requirements?
        i. Assessment Notes: No - Provider signature is included but no mention of the provider prior to the signature, Time needs to be added, and there is no mention of state law requirements.
    c. #8.1: Do the institutional policies and procedures reflect which procedures require informed consent?
        i. Assessment Notes: No - Will need to identify which policy will hold this information.
    d. #8.2: Do informed consent policies and procedures reflect the standards of applicable accrediting organizations?
        i. Assessment Notes: No - Policy needs to be written.
    e. # 9a, 9b, 9c, 9d, 9e, 9f, 9g, 9h, 9i: Do the policies and procedures: Define what is meant by "patient representative" according to state law? Explain when a patient representative or proxy may be consulted to give consent? Include a list with the hierarchy of decision-makers available to medical and clinical staff (e.g., self, legal representative, parent of a minor child, legal guardian, and health care proxy, etc.)? Define what happens when a patient refuses treatment? Outline exceptions to obtaining a patient's informed consent? Include the process of obtaining and documenting consent? Identify the method of documenting consent: form, medical record, progress notes, etc.? Detail the mandatory components of an informed consent document for your facility? Include the definition and limits of "therapeutic privilege" if applicable in your state?
        i. Assessment Notes: No - Policy needs to be written.
2. **Audit**
    a. #12e: Are audits of patient medical records randomly conducted to ensure proper documentation of informed consent including: Who made the decision (e.g., the patient, the patient's legal representative)?
        i. Assessment Notes: No - Will be added to peer review.
3. **Education and Training**
    a. #14: Is adoption of a "teach back" practice in obtaining informed consent encouraged?
        i. Assessment Notes: No - Will be added to SOP.

2026 Q1 Quarterly Risk Assessment Action Plan

6 Activities will correct and prevent 17 findings by October of 2026.

CY26 ECRI Self-Assessment Tool for Informed Consent - Findings and Action Plan

Action Plan:

CY25 Goals	CY25 Activities (What, Who, When)	CY25 Performance
		3 & 6 Month Follow Up
Governance	• Informed consent process needs to be fully assessed to determine whether the process facilitates patient understanding of proposed risks, benefits, and alternatives. • Informed consent needs to be inclusive of all CMS elements including name of provider, patient and/or legal representative's signature, time of signature, and whether there are state law requirements. • Discover if the institutional policies and procedures reflect which procedures require informed consent and reflect the standards of applicable accrediting organizations and then correct if needing correction. • Create a policy that covers the following: Do the policies and procedures: Define what is meant by "patient representative" according to state law? Explain when a patient representative or proxy may be consulted to give consent? Include a list with the hierarchy of decision-makers available to medical and clinical staff (e.g., self, legal representative, parent of a minor child, legal guardian, and health care proxy, etc.)? Define what happens when a patient refuses treatment? Outline exceptions to obtaining a patient's informed consent? Include the process of obtaining and documenting consent? Identify the method of documenting consent: form, medical record, progress notes, etc.? Detail the mandatory components of an informed consent document for your facility? Include the definition and limits of "therapeutic privilege" if applicable in your state? o Patient survey or other study needs to be conducted by July 2026 to quantify patient understanding. o Study of current practices needs to be conducted by July 2026 to create a new policy and SOP to address issues discovered. o Training needs to be conducted by August of 2026 to align all clinic practices with new policy and SOP. o Led by Medical Director and including Operations Manager and Clinical Office Supervisor to complete evaluation and develop and implement the new policy by August of 2026 and present to the Governing Board by October 2026 for approval.	May 2026 – Aug 2026 – Oct 2026 –
		3 & 6 Month Follow Up
Audit	• Peer review process needs to be amended to include ensuring that proper documentation of informed consent includes who made the decision (e.g., the patient, the patient's legal representative)? o Medical Director and/or Operations Managers to provide training to team at huddles by August 2026.	May 2026 – Aug 2026 – Oct 2026 –
		3 & 6 Month Follow Up
Education and Training	• Training process for informed consent to include the "teach back" method. o Medical Director and/or Operations Managers will provide training to appropriate team members by August 2026.	May 2026 – Aug 2026 – Oct 2026 –

Questions?