NOTE: THIS IS A SAMPLE INFORMED CONSENT POLICY. IT MAY NEED TO BE MODIFIED TO COMPLY WITH LAWS, REGULATIONS OR ACCREDITATION STANDARDS APPLICABLE TO A PARTICULAR PROVIDER. SIMILARLY, THE POLICY AND ITS APPLICATION MAY NEED TO BE MODIFIED IN PARTICULAR CIRCUMSTANCES. USERS SHOULD REVIEW THE POLICY WITH QUALIFIED LEGAL COUNSEL BEFORE IMPLEMENTING OR APPLYING THE POLICY. THIS POLICY DOES NOT ESTABLISH AN ATTORNEY-CLIENT RELATIONSHIP OR CONSTITUTE LEGAL ADVICE.

POLICY TITLE: INFORMED CONSENT OR REFUSAL TO CONSENT TO CARE

PURPOSE. To ensure that patients receiving care or treatment at HOSPITAL are properly informed of the relevant risks, benefits, and alternatives before receiving care so that they may make informed decisions concerning their health care, and to ensure that the patient’s consent or refusal of treatment is appropriately documented in the medical record.

POLICY. Except in emergencies, practitioners who provide care or treatment at HOSPITAL shall, before providing treatment, obtain and document informed consent or refusal of treatment from the patient, the patient’s advance directive, or the patient’s authorized surrogate decision-maker.

PROCEDURE.

1. Responsibility for Obtaining Informed Consent. The treating or supervising practitioner is ultimately responsible for discussing the proposed care with the patient, obtaining valid informed consent from the patient or their authorized surrogate decision-maker, and ensuring that valid consent or refusal of consent is documented in the medical record. The treating or supervising practitioner may utilize their staff to help obtain or document the patient’s consent or refusal. HOSPITAL personnel may help document that informed consent or refusal was obtained consistent with this Policy. (I.C. § 39-4508).

2. Process for Obtaining Informed Consent. Except in emergencies, practitioners should comply with the following process when obtaining and document informed consent or refusal of treatment.

   a. General Consent Form. Upon registration for admission or outpatient care, HOSPITAL shall require that the patient or their surrogate execute HOSPITAL’s general consent form. The general consent form is usually sufficient to cover routine lab tests, diagnostic tests, pharmaceuticals, radiology, non-invasive procedures or care, etc. Other services require specific written consent as described below.

   b. Specific Written Consent. In addition to HOSPITAL’s general consent form, the treating practitioner shall obtain and document specific written informed consent for: (1) all surgical cases, including all procedures listed as a surgical procedure by CMS or HOSPITAL’s billing coding system, but excluding simple laceration repair and minor dermatological procedures performed in outpatient settings; (2) administration of anesthesia; (3) experimental procedures or treatment; (4) abortion; (5) administration of blood or blood products if not related to the surgery/invasive procedure and otherwise covered in the surgical consent; (6) radiation therapy; (7) invasive medical imaging; (8) diagnostic procedures that carry a significant, material risk; (9) circumcision; (10) sterilization; (11) continuation of a do-not-resuscitate or – intubate order (DNR or DNI) during surgery if the patient has a DNR or DNI order in place; and (12) any other procedure or treatment that requires a specific informed consent according to Medical Staff Rules or Policies.

   c. Timing of Consent. Except in emergencies, informed consent must be obtained prior to the proposed treatment or procedure. Where possible, consent should be obtained sufficiently in
advance to allow the patient or their surrogate time to consider and make an informed decision. Consent should not be obtained so far in advance that circumstances are likely to change. The consent should be obtained when the patient is not sedated or the patient’s judgment is not otherwise impaired.

d. Discussion with Patient or Surrogate. In obtaining informed consent, the practitioner or their delegate should generally discuss with the patient or their surrogate: (1) the need for treatment; (2) the nature of the treatment; (3) the reasonably probable benefits of the treatment; (4) the significant risks, side effects and potential consequences of the proposed treatment; (5) treatment alternatives with their associated benefits and risks; and (6) the names of practitioners who will perform significant aspects of the treatment. [MODIFY IF RESIDENTS WILL BE PERFORMING ANY SURGICAL PROCEDURES]. The practitioner should communicate in a manner to ensure that the patient or surrogate understands the facts, risks, and benefits relevant to the proposed treatment. The practitioner may use written materials, forms, photographs, videos or other materials to help communicate relevant issues. Where language barriers or other circumstances may impede effective communication, the practitioner may utilize appropriate HOSPITAL resources, including interpreters or translators. (See Policy _____, ____________). At all times, the treating practitioner remains ultimately responsible for ensuring that he or she has obtained and documented appropriate informed consent from the patient or their authorized surrogate decision-maker.

e. Content of Consent Form. A properly executed consent form should contain at least the following: (1) specify that the treatment is to be rendered at HOSPITAL, or identify the other facility at which the treatment will be rendered; (2) identify the specific procedure(s) or other treatment for which consent is given; (3) identify practitioner(s) who will perform significant aspects of the procedure or treatment; (4) summarize significant risks and alternatives; (5) state that the procedure or treatment and associated benefits, risks, and alternatives were explained to the patient or the patient’s authorized surrogate decision-maker; (6) state that the patient’s or surrogate’s questions have been answered to their satisfaction; (7) state that the patient or their surrogate consents to the treatment or procedure; (8) contain the patient’s or their surrogate’s signature along with the date and time of the signature; (9) if signed by the patient’s surrogate, state the surrogate’s authority; and (10) contain the treating practitioner’s signature confirming that informed consent was obtained. [MODIFY IF HOSPITAL WANTS CONSENTS TO BE WITNESSED OR VERIFIED BY HOSPITAL STAFF]

f. Documentation in Medical Record. The patient’s or surrogate’s informed consent must be documented in the patient’s medical record at HOSPITAL. Upon completion, HOSPITAL personnel will place HOSPITAL’s general consent form in the patient’s medical record. If the treating practitioner uses additional or specific consent forms to help document the patient’s informed consent, such forms should also be placed in the patient’s medical record at HOSPITAL. In addition to consent forms, the treating practitioner should document in the chart notes or other relevant portion of the medical record that he or she discussed the treatment, risks, benefits, and alternatives with the patient or their surrogate decision-maker and obtained the patient’s informed consent or refusal to consent to care.

g. Updating Consent Forms and Materials. Any consent forms or other written material used to explain procedures and associated risks or benefits should be periodically reviewed by the practitioner to ensure that information contained in the forms is current and accurate. Although forms may help in obtaining and documenting informed consent, a consent form is not a substitute for the communication that should occur between the treating practitioner and the patient or surrogate to ensure that the patient or surrogate have sufficient understanding to ensure their consent is informed.

h. Oral Consent. In rare circumstances, it may be necessary to obtain the patient’s or their surrogate decision-maker’s consent by telephone. In such cases, the practitioner should immediately document the phone conversation in the medical record, and fax or forward a written consent form to the patient or their surrogate to complete and return to HOSPITAL for inclusion in the medical record.
i. **Verification of Consent.** [INCLUDE IF HOSPITAL WANTS TO REQUIRE SPECIFIC HOSPITAL PERSONNEL TO CHECK THE MEDICAL RECORD TO ENSURE INFORMED CONSENT IS DOCUMENTED BEFORE CERTAIN KINDS OF TREATMENT, E.G., SURGERY]

j. **Scope and Duration of Consent.** Informed consent is generally limited to the specific treatment or course of treatment identified in the communication with the patient and any incidental, included procedures. The practitioner should obtain and document the patient’s consent if (1) new or different treatment is contemplated; (2) the circumstances have changed; (3) a significant lapse in time (e.g., 30 days) has occurred since the original consent was obtained; or (4) the patient or their surrogate expresses doubts or objections suggesting that they may withdraw consent, or may not understand the relevant risks or benefits associated with the procedure.

j. **Withdrawal of Consent.** A competent patient or their surrogate generally may withdraw their consent at any time. The practitioner should address the patient’s or surrogate’s concerns before continuing treatment.

3. **Persons Who May Consent to or Refuse Care.**

a. **Adults Who are Competent.** A person may consent to or refuse their own health care or treatment if they have intelligence and awareness sufficient for him or her generally to comprehend the need for, the nature of and the significant risks ordinarily inherent in, the contemplated care or treatment. (I.C. § 39-4503). The treating health care practitioner should assess and document whether the patient has sufficient capacity to provide informed consent or refusal of consent. The practitioner should beware circumstances where the patient may be medicated, sedated, or otherwise impaired or unable to comprehend the risks and benefits of the proposed treatment.

b. **Adults Who Are Not Competent.** If a patient lacks capacity to consent to their own care as described in section 3(a) and there is no advance directive as described in section 7, below, consent should be obtained from the patient’s authorized surrogate decision-maker in the following order of priority:

   (1) The court-appointed guardian or, if there is no guardian, the court-appointed conservator for the patient.

   (2) A person who is designated in a durable power of attorney to make health care decisions on behalf of the patient. In Idaho, the durable power of attorney is often combined with a living will.

   (3) If married, the patient’s spouse.

   (4) An adult child of the patient.

   (5) The patient’s parent. Either parent may consent to the care of their child. Absent a court order to the contrary, a parent may consent to the care of their child even if they are not the custodial parent.

   (6) A person identified in the parent’s executed delegation of parental authority to make healthcare decisions.

   (7) Any relative representing himself or herself to be an appropriate, responsible person to act under the circumstances, e.g., an adult sibling, grandparent, etc.
Any other competent individual representing himself or herself to be responsible for the health care of the patient, e.g., a babysitter, teacher, coach, etc. (I.C. § 39-4504). The surrogates must themselves have sufficient capacity to consent to care as described in section 3(a), above. The surrogate cannot override the prior informed consent, refusal of consent, or advance directive given by a patient while the patient was competent. (Id.).

c. Minors. Minors generally lack legal capacity to consent to their own health care. (I.C. § 39-4504). Practitioners should generally obtain informed consent from an authorized surrogate unless one of the following exceptions apply:

(1) Minor is Emancipated. A minor who is emancipated may consent to their own health care if they otherwise have sufficient capacity as described in section 3(a), above. A minor is emancipated if:

   (a) the minor is married or has been married in the past even if the minor is no longer married (see I.C. § 18-604(3));

   (b) the minor is serving in the active military (see I.C. 18-604(3));

   (c) the minor has been declared to be emancipated by the court (see I.C. § 16-2403(1)); or

   (d) the minor has rejected the parent-child relationship, is living on his or her own, and is self-sufficient (e.g., the minor has his or her own job; has his or her own insurance; pays his or her own bills; etc.). (See I.C. § 66-402(6)). The practitioner should document the facts leading to this conclusion.

(2) Statute Authorizes Minor to Consent. A minor may consent to their own care if a specific statute allows them to consent. Federal and state statutes allow minors to consent to their own care in the following circumstances:

   (a) Emergencies. Under EMTALA, minors may consent to their own emergency medical screening exam and, if the exam reveals a potential emergency condition, minors may consent to initiation of stabilizing treatment. If there is no emergency condition, the practitioner should obtain consent from an authorized surrogate before providing further treatment. (See EMTALA Interpretive Guidelines).

   (b) Contraceptives. Minors who have sufficient intelligence and maturity to understand the nature and significance of the treatment may consent to examinations, prescriptions, or devices regarding contraception. (See I.C. § 18-603).

   (c) Infections or Communicable Diseases. Minors age 14 or older may consent to their own testing or treatment for infectious or communicable diseases specified in DHW regulations. Parents are not liable for payment of such care that is given without the parent’s consent. (See I.C. § 39-3801; IDAPA 16.02.10.015.11.c).

   (d) Mental Illness. Minors age 14 or older may consent to their own hospitalization for observation, diagnosis, evaluation and treatment for a mental condition. The hospital must notify the parents. (See I.C. § 66-318(1)(b)).
(e) **Drug Treatment or Rehabilitation.** Minors may consent to their own drug treatment or rehabilitation. If the minor is under age 16, the practitioner should notify the parents. If the minor is age 16 or older, the practitioner may not notify the parents without the minor’s consent. (See I.C. § 37-3102).

(f) **Blood Donations.** Minors who are age 17 or older may consent to donate blood if they are not compensated for the donation. (See I.C. § 39-3701).

(3) **Minor Has Sufficient Maturity.** In exceptional cases, practitioners may rely on consent or refusal provided by a sufficiently mature minor if the practitioner in good faith believes that: (1) the minor has sufficient maturity, intelligence and awareness to comprehend the need for, the nature of, and the significant risks ordinarily inherent in, the contemplated care or treatment as described in paragraph 3(a), above; and (2) the practitioner believes that allowing the minor to consent to or refuse their own care is in the patient’s best interest and is consistent with appropriate medical judgment. In making this determination, the practitioner should consider and document relevant factors, including: (1) the minor’s chronological age (e.g., a minor who is age 17 is more likely to be deemed competent than a minor who is age 14); (2) the minor’s maturity, intelligence, and judgment; and (3) the nature of the procedure or treatment (e.g., a mature minor may be competent to consent to routine, minimally risky procedures, but lack sufficient maturity or understanding to comprehend or consent to serious, invasive or significant procedures). **Because the status of this exception is unsettled in Idaho, practitioners should normally obtain consent from the minor’s authorized surrogate decision-maker. Pracititioners should carefully consider and document the foregoing factors before relying on the minor’s consent. In questionable cases, the practitioner should consult with HOSPITAL’S risk manager and/or attorney.**

(4) **Pregnant Minors.** Pregnant minors generally lack capacity to consent to their own care or the care of their fetus unless one of the foregoing exceptions apply (e.g., the minor is emancipated; seeks treatment for a sexually transmitted disease or other care authorized by statute; or has sufficient maturity to make informed health care decisions; etc.). In most cases, consent should be obtained from the minor’s authorized surrogate decision-maker. Pursuant to Idaho law and except in limited emergency cases, a minor seeking an abortion must generally obtain parental or judicial consent before an abortion may be performed. (See I.C. § 18-602 et seq.)

(5) **Minors Who Are Parents.** Minors who are parents may generally consent to or refuse health care for their own children so long as the minor parent has sufficient maturity, intelligence and awareness to comprehend the need for, the nature of and the significant risks ordinarily inherent in, the contemplated care or treatment as described in paragraph 3(a), above. (See I.C. § 39-4504). If the minor parent lacks such maturity, the practitioner should seek consent from other authorized surrogate decision-makers as described above.

4. **Emergencies.** In an emergency situation, practitioners may initiate appropriate care without obtaining prior informed consent if: (1) the practitioner determines that there is a substantial likelihood that the patient’s life or health may be seriously endangered without immediate treatment; (2) the patient lacks capacity to consent, and an authorized surrogate decision-maker is not readily available to consent; and (3) the practitioner acts in good faith without knowledge of facts suggesting that the treatment would be contrary to the patient’s prior directives (e.g., the patient’s POST, DNR, living will, or similar prior directions). Practitioners shall make a reasonable investigation to confirm whether the patient has a valid POST, DNR, or advance directive. The practitioner must document in the medical record the facts that make the situation an emergency. Emergency treatment under this exception may continue until the patient gains decision-making capacity, or until the surrogate decision-maker is available to make decisions for the patient, at which time informed consent should be obtained. (See I.C. § 39-4504).
5. **Court-Ordered Treatment.** Treatment may be provided to an individual without the individual’s informed consent if ordered by a court with jurisdiction over HOSPITAL. HOSPITAL may object to providing the treatment if the treatment is contrary to the patient’s best interests or otherwise endangers HOSPITAL personnel.

6. **Treatment at Request of Law Enforcement.** In general, practitioners must obtained informed consent from a patient to provide treatment to a patient who is in the custody of law enforcement. If requested by a police officer, Idaho law allows physicians, registered nurses, phlebotemists, and certain other qualified practitioners to draw blood from a motorist with an Idaho drivers license for evidentiary testing. The practitioner should decline to draw the blood if the patient objects, is uncooperative, or the practitioner is otherwise concerned that drawing blood may pose a safety risk. If the requesting police officer believes that the patient has committed certain crimes (including aggravated DUI or vehicular manslaughter), the officer may order a qualified practitioner to draw blood for testing; however, the practitioner may refuse if he or she believes that the draw may result in serious bodily injury to patients or hospital personnel, or if the test is contraindicated by the patient’s condition. (See I.C. § 18-8002 et seq.)

7. **Advance Directives.** Any authentic expression of a competent patient’s informed treatment decisions should be honored. The patient may express or document his or her wishes formally through a Living Will, Durable Power of Attorney, Physician’s Order for Scope of Treatment (“POST”), or similar document, but these are not the only means by which a competent patient may express his or her wishes. The patient may also express or document his or her decisions through any other reliable means, whether orally, written, or otherwise. Practitioners should generally document and comply with a competent patient’s prior expressed wishes. (See Policy ____, ________________). (I.C. § 39-4509 et seq.)

8. **Refusal of Treatment.**

   a. **By Competent Adult.** A competent adult generally has the right to refuse or withdraw from participation in the treatment. (I.C. § 39-4502(6)). The practitioner should document that he or she explained the risks and benefits of the proposed treatment and alternatives as described in section 2(d), above. In addition, the practitioner should confirm and document (1) the patient’s capacity to make the decision; (2) the practitioner’s efforts to explain the risks and benefits of the treatment; and (3) the patient’s informed refusal. (See Policy ____, ________________). The communication and refusal should be documented in the medical record.

   b. **By Surrogate.** Idaho law generally allows a surrogate to refuse care to the extent that such refusal is not inconsistent with the patient’s prior expressed wishes. (See I.C. § 39-4504 and -4514). However, in limited circumstances, a surrogate’s decision to forego necessary medical care may constitute child neglect or vulnerable adult neglect. If the circumstances warrant, the practitioner may be required to report the possible neglect to appropriate state agencies. (See Policy ____, ________________). In the case of a child, the practitioner and/or HOSPITAL may seek an emergency order from court authorizing treatment. (See Policy ____, ________________). (I.C. § 16-1627).

   c. **By Guardian of Developmentally Disabled Person.** Except as described below, a court-appointed guardian for a developmentally disabled person generally cannot refuse necessary care when the effect of withholding such treatment would seriously endanger the life or health and well-being of the person. If the guardian refuses such care, the practitioner may generally provide the necessary care over the guardian’s objection. A guardian may refuse care and the practitioner may withhold or withdraw artificial life-sustaining procedures care from a developmentally disabled person if (1) the patient has an incurable condition certified by the patient’s attending physician and one other physician to be terminal such that the artificial life-sustaining procedures would not result in the possibility of saving or significantly prolonging the life of the patient, and would only serve to prolong the moment of the patient’s
death for a period of hours, days or weeks, and both physicians certify that death is imminent whether or not artificial life-sustaining procedures are used; or (2) the attending physician and one other physician certify that the patient is in a persistent vegetative state which his irreversible and from which the respondent will never regain consciousness. (See I.C. § 66-401 et seq.)

References

Idaho Code § 39-4501 et seq.

Idaho Code § 66-401 et seq.

Medicare CAH Conditions of Participation, 42 C.F.R. § 485.638(b)(3); see also 42 C.F.R. §§ 482.13(b)(2), 482.24(c)(2), 482.51(b)(2), and CMS Survey and Certification Memorandum S&C-07-17 (4/13/07)


Related Policies

Policy No. ____, Agreement to Pay for Treatment
Policy No. ____, Advance Directives
Policy No. ____, Mental Health Holds
Policy No. ____, Consent for Participation in Research
Policy No. ____, Authorization to Disclose Protected Health Information
Policy No. ____, Addressing Communication Barriers and Patients
Policy No. ____, Reporting Abuse, Neglect, or Injury from Crime
Policy No. ____, Withdrawing from Providing Treatment Due to Professional or Conscience Concerns

[Others?]