HAWAII HEALTH SYSTEMS CORPORATION *Quality Healthcare for All* **PROCEDURE**	**Department:** LEGAL	**Policy No.** **PAT 0015B**
		Supersedes Policy No.
Subject: **INFORMED CONSENT**	**Approved By:** [signature] By: Edward N. Chu. Its: HHSC President & CEO	**Approved Date:** February 27, 2025
		Last Reviewed: February 27, 2025

I. PURPOSE:

To outline the responsibilities for obtaining informed consent from patients or their authorized representatives.

II. DEFINITIONS:

"Adult" means an individual aged eighteen (18) or older.

"Advance health care directive" means individual instruction or a power of attorney for health care that is in writing, notes the date of its execution, and is signed by the patient and signed and witnessed by at least two individuals or a notary public in Hawaii.

"Advance mental health care directive" means a written document declaring instructions regarding the patient's mental health care treatment that notes the date of its execution, is signed by the patient, and signed and witnessed by two competent adults or acknowledged before a notary public in Hawaii.

"Capacity/Decisional capacity" means an individual has the ability to understand the significant benefits, risks, and alternatives to proposed health care treatment and to make and communicate a health care decision.

"Caregiver" means a person who is at least eighteen years of age and is: 1) related by blood, marriage, or adoption to the minor, but who is not the legal custodian or guardian of the minor; or 2) has resided with the minor continuously during the immediately preceding period of six months or more.

"Designated health care agent" means an individual designated by the patient, in a power of attorney for health care document or advance health care directive to make health care decisions for the patient.

"Designated mental health care agent" means an individual designated by the patient in an advance mental health care directive to make mental health care decisions for the patient.

"Designated health care decision maker" means a guardian, designated health care agent, or designated surrogate as defined herein.

“Designated surrogate” means an individual that a patient with capacity designates to make health care decisions by personally informing the supervising health care provider of their designation. Such designation must be documented in the medical record of the patient and not subsequently withdrawn.

“Emancipated minor” means a minor who has been married and is the minimum legal age of sixteen (16).

“Facility staff” means individuals employed or contracted to provide services to the facility, excluding physicians and advanced practice practitioners.

“Guardian” means a judicially appointed guardian having authority to make health care decisions for an individual.

“Health care provider” means a physician or advanced practice practitioner that is practicing within their scope of practice for which they have been granted privileges by the hospital.

“Informed consent” is the process by which a patient learns about and understands the purpose, benefits, and potential risks of a medical or surgical intervention and then agrees or refuses to receive such intervention.

“Minor” means an individual that is under the age of eighteen (18) and is not an Emancipated Minor.

“Patient” means an adult or emancipated minor presenting for health care services.

“Primary health care provider” means a physician designated by an individual or their health care agent, to have primary responsibility for the individual’s health care, or in the absence of a designation, or if the designated physician is not reasonably available, a physician who undertakes the responsibility.

“Representative” means any person authorized to make health care and/or mental health care decisions for the patient whether designated or appointed.

“STI” means sexually transmitted infection.

“Surrogate” means an individual, other than a patient’s designated health care agent or guardian, authorized to make health care decisions in accordance with the procedure laid out herein.

III. PROCEDURES:

A. <u>When Informed Consent is Needed</u>

1. Informed consent is needed when the proposed treatment or procedure is invasive, puts the patient at risk, is complex, or is for non-emergent treatment for mental illness. The medical staff and administrative leadership of each facility shall specify the procedures and treatments that require written informed consent; such specified procedures and treatments may be found in Attachment 1 “Procedures and Treatments Requiring Informed Consent.” Examples of such procedures that require informed consent include, but are not limited to:
    a. All surgical procedures performed under general/spinal anesthesia and selected procedures under local anesthesia;
    b. Certain biopsies and excisions;
    c. Radiation;

d. Chemotherapy;
e. Blood transfusions;
f. Certain vascular access procedures;
g. Non-emergent treatment for mental illness;
h. Procedures that require anesthesia.

2. <u>Procedures that Require Special Consent</u> - Certain procedures require special consent as follows:
    a. <u>Opioid Therapy</u>
        i. Any health care provider who is authorized to prescribe opioids shall engage in the informed consent process and get written informed consent on the Opioid Informed Consent form, when prescribing opioid therapy to:
            1) A patient requiring opioid treatment for more than three (3) months; or
            2) A patient who is prescribed benzodiazepines and opioids together; or
            3) A patient who is prescribed a dose of opioids that exceeds ninety morphine equivalent doses.
        ii. This does not apply to orders for opioids that are dispensed for immediate administration to the ultimate user, i.e. inpatient orders for opioids.
        iii. This does not apply to prescriptions provided under Hawaii's Our Care Our Choice Act.
    b. <u>Sterilization of mentally competent patient aged 21 or older **and a Medicaid beneficiary-**</u>
        i. A health care provider must obtain informed consent for sterilization and must offer to answer any questions the patient to be sterilized may have concerning the procedure. The health care provider must provide a copy of the consent form and provide all of the following information to the patient to be sterilized:
            1) Advice that the patient is free to withhold or withdraw consent at any time before sterilization without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the patient might be otherwise entitled;
            2) A description of available alternative methods of family planning and birth control;
            3) Advice that the sterilization procedure is considered to be irreversible;
            4) A thorough explanation of the specific sterilization procedure to be performed;
            5) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;
            6) A full description of the benefits or advantages that may be expected as a result of the sterilization;
            7) Advice that the sterilization will not be performed for at least 30 days except under the following circumstances:
                a) Premature delivery; or
                b) Emergency abdominal surgery.

ii. Informed consent may NOT be obtained while the patient to be sterilized is:
1) In labor or childbirth;
2) Seeking to obtain or obtaining an abortion; or
3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

iii. Informed Consent Form for Sterilization
1) Consent for Sterilization Form (retrieve the most up to date Form HHS-687 at https://medquest.hawaii.gov/en/resources/forms.html) must be filled out by the patient and the physician a minimum of 30 days prior to the sterilization procedure.

iv. Interpreter Services
1) If an interpreter was used in the informed consent process, the interpreter must certify that s/he translated the information and advice presented orally and read the consent form and explained its contents to the patient to be sterilized and that, to the best of the interpreter's knowledge and belief, the individual understood what the interpreter told him or her.

B. When Informed Consent is NOT Needed

1. Emergencies
   a. Informed consent is not required when emergency treatment is needed and the health care provider, using their best judgment, determines that obtaining consent is not reasonably feasible under the circumstances without adversely affecting the condition of the patient's health.
   b. The health care provider shall document the nature of the medical emergency in the patient's medical record.
2. Detrimental to Patient Health
   a. Informed consent is not required in cases where, in the judgment of the health care provider, such information would be detrimental to the patient's mental or physical health or not in the best interest of the patient.
   b. Such action must be consistent with general standards of medical and surgical practice.
   c. The health care provider must document their decision and reasoning in the patient's medical record.
3. Refusal of Information
   a. A patient may elect not to receive any part or all of the information that would otherwise be required to be provided.
   b. Any refusal to receive information must be documented by the health care provider in the patient's medical record.

C. Elements of Informed Consent

1. The following information shall be communicated, in language that the patient will understand, to the patient or the patient's representative prior to obtaining consent for the proposed treatment or diagnostic procedure:
   a. Diagnosis or suspected diagnosis or the condition being treated;
   b. The description of the proposed medical or surgical treatment or diagnostic procedure;
   c. The intended and anticipated result;
   d. The recognized alternative treatments or diagnostic procedures, including the option of not receiving the treatment or diagnostic procedure;

e. The recognized substantial risks of the proposed treatment or diagnostic procedure and the alternative treatments or diagnostic procedure, and the option of not undertaking treatment or diagnosis;
f. The recognized benefits of the proposed treatment or diagnostic procedure, alternative treatments or procedures, and not undertaking any treatment or procedure.
g. Information should also include:
    i. Who will perform the procedure(s)
    ii. Who will administer the anesthesia
    iii. Whether physicians or other medical practitioners, such as residents, advanced practice providers or other applicable students (performing within their scope of practice), other than the operating physician, will be performing important tasks related to the procedure, or examinations or invasive procedures for educational and training purposes. Important tasks include: opening and closing, dissecting tissue, removing tissue, implanting devices. Examinations or invasive procedures conducted for educational and training purposes include, but are not limited to, breast, pelvic, prostate, and rectal examinations.

2. The information can be communicated in writing, orally, or by way of audio visual aids, so long as the conversation between the health care provider and patient or their representative allows for the patient or their representative to make an informed decision.

D. Informed Consent Forms

1. A written consent form, which must be entered into the patient's medical record, is required for patients undergoing anesthesia procedures, but patients with the ability to verbally affirm consent for procedures that do not require anesthesia should have their medical record reflect that consent was given. A properly executed informed consent form contains the following minimum elements:
    a. Name of the facility where the procedure is to take place;
    b. Name of the specific procedure for which consent is being given;
    c. Name of the responsible health care provider(s) who is/are performing the procedure;
    d. Statement that the procedure, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's representative;
    e. Signature of the patient or the patient's representative, the date and time the patient or patient's representative signed, and if the patient is not the signatory, the relationship of the signer to the patient;
    f. Name of the health care provider that conducted the informed consent discussion with the patient or patient's representative; and
    g. Name, signature, and date signed of interpreter, if one was used.
2. If the health care provider elects to have a witness sign the informed consent form, the witness signature shall only attest to the fact that the signatory signed the form.

E. Who Can Consent

1. **A patient who has legal capacity, physical capacity *and* decisional capacity can provide consent for treatment.**
    a. Legal capacity means an adult aged 18 or older.
        a. Minors may have statutory legal capacity in certain cases - see the Minor Consent section of this Policy for guidance
    b. Physical capacity means the patient is conscious and able to communicate a decision regarding their care.
    c. Decisional capacity means an individual has the ability to understand the significant benefits, risks, and alternatives to proposed health care and is able to make and communicate a health care decision.

i. All patients are presumed to have decisional capacity.
ii. The primary health care provider has the responsibility to make the determination as to whether a patient lacks decisional capacity.

2. A spouse or family member has no automatic or assumed legal capacity to consent on behalf of a patient without being designated by way of one of the procedures described below.

3. **Patient Lacking Capacity with a Designated Health Care Decision Maker**
   a. If a patient lacks the necessary capacity, but has a guardian, designated surrogate, or designated health care agent, as defined below, then the guardian, designated surrogate, or designated health care agent can make health care decisions for the patient.
      i. A guardian is someone who is authorized by the courts to make health care decisions for the patient.
         a) Absent a court order to the contrary, a health care decision of a guardian appointed by the courts takes precedence over that of a designated health care agent or designated surrogate.
      ii. A designated surrogate is an individual who was designated by the patient, when the patient had capacity, to make health care decisions for the patient. Designation of a surrogate by the patient can be done by personally informing the supervising health care provider of their designation. Such designation must be documented in the medical record of the patient. A valid designation may be subsequently withdrawn by a patient with capacity.
      iii. A designated health care agent is someone authorized by the patient, in their power of attorney for health care decisions or advance health care directive, to make health care decisions for the patient.
         a) A decree of annulment, divorce, dissolution of marriage or legal separation revokes a previous designation of a spouse as a designated health care agent unless otherwise specified in the decree or in a power of attorney for health care decisions.
         b) An advance health care directive that conflicts with an earlier advance health care directive revokes the earlier directive to the extent of the conflict.
      iv. A designated health care agent or a designated surrogate may not consent to admission of a patient to a psychiatric facility unless specifically authorized.
   b. <u>Mental Health Care</u>
      i. A patient may designate a competent adult to act as a designated mental health care agent to make all mental health care treatment decisions on behalf of the patient when the patient lacks capacity. This can be done by way of a written advance mental health care directive or can be a part of a written advance health care directive.
         a) A decree of annulment, divorce, dissolution of marriage or legal separation revokes a previous designation of a spouse as a designated mental health care agent unless otherwise specified in the decree or in an advance mental health care directive.
         b) An advance mental health care directive that conflicts with an earlier advance mental health care directive revokes the earlier directive to the extent of the conflict.
      ii. The authority of the designated mental health care agent is only effective upon a determination that the patient lacks capacity.
         a) The patient is presumed to have capacity.
         b) The supervising health care provider, who is a physician, and one other physician or licensed psychologist, must both make a

determination that the patient lacks capacity, after both individuals have conducted an examination of the patient.

4. **Patient Lacking Capacity *without* a Designated Health Care Decision Maker (*Consensus Surrogacy*)**
   a. If a patient lacks capacity and does not have a designated health care decision maker, or the designated health care decision maker is not reasonably available, a surrogate decision maker may be appointed to make health care decisions for the patient by way of the following process:
      i. Upon a determination by the primary physician that the patient lacks decisional capacity to provide informed consent to or refuse medical treatment, the physician or their designee shall make reasonable efforts to notify the patient of the patient's lack of capacity.
      ii. The primary physician or their designee shall make reasonable efforts to locate as many interested persons as practicable. The primary physician or their designee may rely on such individuals to notify other family members or interested persons.
         a) Interested persons means the patient's spouse, unless legally separated or estranged, a reciprocal beneficiary, any adult child, either parent of the patient, an adult sibling or adult grandchild of the patient, or any adult who has exhibited special care and concern for the patient and who is familiar with the patient's personal values.
      iii. Upon locating interested persons, the primary physician, or their designee, shall inform such persons of the patient's lack of decisional capacity and that a surrogate decision-maker should be selected for the patient.
      iv. Interested persons shall be informed that they should make reasonable efforts to reach a consensus as to who among them shall make health care decisions on behalf of the patient and that the person selected should be the person who has a close relationship with the patient and who is most likely to be currently informed of the patient's wishes regarding health care decisions.
      v. The supervising health care provider shall require a surrogate to provide a written declaration under the penalty of false swearing stating facts and circumstances reasonably sufficient to establish the claimed authority.
      vi. If any of the interested persons disagrees with the selection or the decision of the surrogate, or, if after reasonable efforts the interested persons are unable to reach a consensus as to who should act as the surrogate decision maker, then any of the interested persons, who were involved in the discussions to choose a surrogate, may initiate guardianship proceedings with the court.
   b. The surrogate chosen by consensus may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the primary physician and a second independent physician certify in the patient's medical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to have any neurological response in the future.
   c. All health care decisions that a surrogate chosen by consensus makes is effective without judicial approval.

d. A surrogate chosen by consensus may not consent to the admission of a patient to a psychiatric facility.
e. If there are no known interested persons, obtain guardianship or a court order to provide further treatment.

F. <u>Minor Consent</u>

1. Minors shall be admitted and/or treated only with the consent of a parent or a legal guardian ***<u>except for</u>***:
   a. <u>Services relating to pregnancy, family planning, and venereal disease</u>: Minors fourteen (14) years of age and older, who:
      i. Professes to be pregnant; or
      ii. Professes to be infected with or at risk of exposure to or has been exposed to a STI; or
      iii. Is seeking family planning services

      may consent to medical care and services relating to pregnancy, family planning, and venereal disease, also referenced in this policy as STI.
      i. "Relating to pregnancy and venereal disease" includes birth control and STI treatment and diagnosis.
      ii. "Family planning" includes counseling and medical care designated to facilitate family planning.
      iii. "Medical care and services" means the diagnosis, examination, and administration of medication in the treatment of venereal diseases, pregnancy, and family planning services.
      iv. No consent given under this section shall be subject to later disaffirmance by reason of the minor patient's minority.
      v. No consent of any other person or persons shall be necessary to authorize the provision of medical care and services to the minor.
   b. <u>Abortion:</u> A minor may provide informed consent to an intentional termination of pregnancy provided that the physician makes a determination, and documents such determination in the medical record, that:
      i. The minor understands the nature and consequences of the medical needs and treatment chosen; and
      ii. The medical services are appropriate to the minor's needs.
   c. <u>Mental Health Services</u>: Minors fourteen (14) years of age or older may consent to mental health outpatient treatment or counseling services if, in the opinion of the licensed mental health professional, the minor is mature enough to participate intelligently in the mental health outpatient treatment or counseling services.
      i. Consent of the minor's parent or legal guardian shall be required to prescribe medication or to place the minor into an out of home or residential treatment program.
      ii. Such mental health services shall include involvement of the minor's parent or legal guardian, unless the mental health professional, after consulting with the minor, determines that the involvement would be inappropriate. The licensed mental health professional shall state in the minor's medical record whether they attempted to contact the minor's parent or legal guardian, whether such attempt was successful, or why it would be inappropriate to contact the minor's parent or guardian.
      iii. A minor may not repeal consent provided by a parent or legal guardian on the minor's behalf.
      iv. A parent or legal guardian may not repeal consent given by the minor on the minor's own behalf.

d. Minors without support:

   i. A licensed health care provider may provide medical care to a "minor without support" who consents to primary medical care if they in good faith believe that the minor is without support and that:

      a) The "minor without support" understands the significant benefits and risks of the proposed primary medical care and can communicate an informed consent; and

      b) The primary medical care is for the minor's benefit.

   ii. "Minor without support" means a person who is at least fourteen (14) years of age who is not under the care, supervision, or control of a parent, custodian, or legal guardian.

   iii. "Primary medical care" means health services that include screening, counseling, immunizations, medication, and treatment of illnesses and medical conditions customarily provided in an outpatient setting. It does not include invasive care, such as surgery, that goes beyond standard injections, laceration care or treatment of simple abscesses.

e. Emancipated Minors: a minor who has been married shall be deemed to be emancipated and shall be regarded as though he or she were of legal age and shall have the authority to provide consent to all health care treatment as if they reached the age of majority under civil law. In Hawaii, the minimum legal age of marriage is sixteen (16). An affirmative statement by the minor patient who is sixteen (16) or older that s/he is married is sufficient to treat the minor patient as an emancipated minor. This information shall be documented in the patient's medical record.

f. Minors Incapable of Informed Consent: If a physician determines that a minor in the situations described in sections F (1) (a-e), is not capable of providing informed consent, the practitioner, shall contact their Regional Risk Management for guidance.

2. **Special Situations Involving Minors:**

   a. *Minor Children of Minor Mothers***:** Minor mothers and minor fathers have the authority to consent to health care treatment for their children.

   b. *Adopted Minor:* If a minor has been legally adopted, adoptive parents may consent to health care treatment of the minor child.

   c. *Stepparents:* Unless the stepparent has legally adopted the minor child, a stepparent does not have the authority to consent to health care treatment of the minor child.

   d. *Minors in the Process of Adoption:* If the child has been placed for adoption, but the prospective, adoptive parents have not been given legal custody, the prospective parents cannot consent unless they have been given written authority.

   e. *Minors of Divorced Parents:* Always attempt to obtain consent of the parent having legal custody under a court order. If the order does not include disposition of legal custody or legal custody is jointly held, then the consent of either parent is sufficient. In the case of a disagreement between parents, the parent having legal custody has the final authority. If further treatment is necessary, the inability to secure valid consent should be documented and the parents advised to obtain a legal resolution. If further treatment cannot await legal resolution, the facility may petition Family Court for consent.

f. *Minors in Custody of Department of Human Services (DHS):* Upon the request of the State DHS, and without regard to parental consent, a physician licensed to practice medicine in Hawaii shall perform an examination of the minor to determine the nature and extent of harm or threatened harm to the minor.

g. *Minors in Custody of Department of Public Safety:* Consent from the parents or guardians is required to provide health care treatment to minors in custody of the Department of Public Safety. Assistance in locating parents or guardians can be sought from Child Welfare Services or Court Probation. If the parents or guardian objects to treatment, the Probation Officer or Department of Public Safety may request an order from Family Court.

h. *Caregiver Consent:* Excluding minors placed under the care of Child Welfare Services, a caregiver who possesses and presents a notarized affidavit of caregiver consent for a minor's health care, may consent on behalf of a minor to primary and preventative medical care, diagnostic testing, and other medically necessary health care and treatment. The affidavit must have the following elements:

i. Caregiver's name and current home address and birthdate;
ii. Number of caregiver's Hawaii driver's license or state identification card;
iii. Relationship of caregiver to minor;
iv. Minor's name and birthdate;
v. Length of time minor has resided with the caregiver;
vi. Caregiver's oath affirming the truth of the matter asserted;
vii. Signature of minor's parent, guardian, or legal custodian consenting to the caregiver's authority over the minor's health care unless the affidavit states that the caregiver has been unable to obtain such signature and describes the attempts made to obtain such signature; and
viii. A general statement that the declaration does not affect the rights of the minor's parent or guardian; does not give the caregiver legal custody of the minor, the minor's parent or guardian may at any time rescind the affidavit by providing written notification; and any person who relies in good faith on the affidavit of the caregiver consent for a minor's health care has no obligation to conduct any further investigation and shall not be subject to civil or criminal liability or professional disciplinary action due to that reliance.

G. <u>Responsibilities of the Health Care Provider</u>

1. The health care provider that ordered the procedure or will be performing the procedure is responsible for:
    a. Having the informed consent discussion with the patient or patient's representative; and
    b. Ensuring that the properly executed informed consent form is completed before conducting the procedure, and placed in the patient's medical records.
2. In certain cases, this might require that the informed consent process occur with more than one health care provider. For example, for surgery with general anesthesia, the surgeon and the anesthesiologist each have a responsibility to discuss the risks and benefits of their respective proposed plans with the patient prior to the surgery.

H. Responsibilities of Facility Staff

1. Facility staff is responsible for ensuring that informed consent was obtained prior to the administration of pre-operative or pre-procedure medication, or the initiation of the procedure.
2. Facility staff are NOT responsible for securing the patient's informed consent, for obtaining the patient's or patient's representative's signature on the informed consent form, or for providing the information necessary for the informed consent.
3. If it becomes apparent that a patient has significant questions about the nature of a procedure or its risks, benefits, etc. facility staff should immediately inform the physician, advanced practice practitioner, or physician assistant that ordered or will be performing the procedure so that s/he may follow up with the patient.

I. Alternative Methods for Obtaining Consent

1. Consent by telephone: This method should only be used if the person having legal responsibility to consent for the patient is not otherwise available and treatment cannot be withheld until such time as s/he is available.
   a. The health care provider shall discuss the elements of informed consent listed in this policy.
   b. Two facility staff shall be present on the call for the entire duration of the call to witness the informed consent process.
   c. The informed consent form shall note the date, time, method of consent, and the name and relationship of the patient representative.
   d. The informed consent form shall include the signature of the two facility staff witnesses, along with their names, titles, and date indicating that they witnessed and signed the informed consent form.
   e. The patient representative should be asked to come to the hospital, if possible, to sign the informed consent form or the informed consent form can be faxed to the patient representative and received by fax from the representative.
   f. The documentation in the patient's medical record shall explain why consent was obtained in this manner.
2. Consent with Communication Barriers: If the patient or patient representative is unable to communicate because of language or other communication barriers, interpreters shall be made available.
   a. When interpreters are used, the medical record should be noted with the interpreter's name, position, and company that is providing the interpreter services.
   b. A witness shall be present for the entire informed consent process in addition to the interpreter.
   c. The interpreter, if present, and witness shall sign as witnesses to the patient's or patient's representative's signature.

IV. AUTHORITY:

- Hawaii Revised Statute (HRS) §325-16
- HRS §327E-5
- HRS §327G-10
- HRS §329-38.5
- HRS §334E-1
- HRS §386-28
- HRS §453-18
- HRS §577-29

- HRS §577A
- HRS §577D-2
- HRS §671-3
- Hawaii Administrative Rules (HAR) Title 16, Chapter 85, Subchapter 4
- Joint Commission Standard RI.01.03.01
- 42 CFR §441.257
- 42 CFR §482.13(b)(2)
- 42 CFR §482.24(c)(2)(v)
- 42 CFR §482.51(b)(2)
- CMS State Operations Manual, Appendix A- Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, tag A-0955

V. ATTACHMENT(S):

- Attachment 1: "Procedures and Treatments Requiring Informed Consent"

VI. REFERENCES:

- Find latest MedQuest Sterilization Informed Consent Form HHS-687 at https://medquest.hawaii.gov/en/resources/forms.html

ATTACHMENT 1

PROCEDURES AND TREATMENTS THAT REQUIRE INFORMED CONSENT

(For Facility Use)