Rancho Los Amigos National Rehabilitation Center

ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT: **INFORMED CONSENT**

Policy No.: B519
Supersedes: November 26, 2019
Revision Date: December 1, 2021

PURPOSE

To ensure patients undergoing complex diagnostic or therapeutic procedure are provided with information necessary to give permission and sign an informed consent prior to treatment.

POLICY

The treating practitioner shall obtain a specific informed consent for complex procedures including but not limited to surgery in the OR, anesthesia, blood transfusions, and advanced invasive procedures outside the OR.

A complete informed consent process must include:

- Nature of the proposed care, treatment, services, medications, interventions or procedures;
- Potential benefits, risks, or side effects, including potential problems that might occur during recuperation;
- Likelihood of achieving goals;
- Reasonable alternatives;
- Relative risks, benefits, and side effects related to alternatives, including the possible result of not receiving care, treatment and services;
- When indicated, any limitations on the confidentiality of information learned from or about the patient; and
- Any potentially conflicting interests, such as research or financial interests.

Except in the case of medical emergencies, no medical care shall be provided at Rancho Los Amigos National Rehabilitation Center unless appropriate consent has been obtained from the patient or from the patient's legal representative.

In the case of a medical emergency, treatment may proceed without the patient's consent if no evidence exists to indicate that the patient or the patient's legal representative would refuse the treatment. A medical emergency condition exists when:

- Immediate services are required for the alleviation of severe pain; or

- Immediate diagnosis and treatment of unforeseeable medical conditions are required, if such conditions would lead to serious disability or death if not immediately diagnosed and treated.

Definitions

Practitioner—the practitioner is defined as any physician, dentist, podiatrist, or mid-level provider such as Certified Registered Nurse Anesthetist, Registered Nurse Practitioner, and Physician Assistant who has been granted specific clinical privileges to perform the treatment or procedure involved.

Decision-Making Capacity—the adult patient presenting him or herself for treatment is assumed to have decision-making capacity unless there is evidence to the contrary. The primary care is responsible for determining the patient's decision-making capacity.

The adult patient demonstrates decision making capacity when he/she is able to understand the given information about diagnosis, treatment, and relationship of the proposed treatment to his/her medical condition; is able to evaluate the risks, benefits, and alternatives of the proposed treatment and to make choices with appropriate reasons; and is able to communicate his/her choice from the treatment options.

Minors (under 18 years of age) may give consent for medical care if one of the following conditions applies:

- Minors on active duty with the United States Forces
- Emancipated minor
- Minors under 18 years of age, married or previously married
- Self-sufficient minors over the age of 15, not living at home, managing own financial affairs

Informed Consent—a practitioner must explain the nature of the treatment, the risks, possible complications, expected benefits, or effects of the treatment, the likelihood of the patient achieving his or her goals, and any potential problems that might occur during recuperation. The practitioner must explain any alternatives to the treatment, including refusal of treatment, and the risks and benefits of each.

Note: Contact Risk Management for any consent related questions.

PROCEDURES

It is the treating physician's responsibility to obtain informed consent. The duty to provide the information necessary to secure the patient's informed consent, and respond to the patient's questions concerning the proposed procedure, is the exclusive duty of the treating physician or the legally authorized designee. Informed consent must be obtained for procedures that are not covered in the general consent or conditions of admissions form.

The physician obtaining the patient's informed consent shall also document, in the medical record: that a discussion was held with the patient or his/her legal representative; the patient or his/her legal representative fully understood the nature of the procedure, including the risk and benefits of agreeing or refusing the procedure; and that informed consent was obtained.

All interpreters are required to interpret the exchange of information between the patient and physician as it relates to the informed consent process. This may include the oral interpretation of the information on the consent form/documents, if it is not printed in the patient's native language and time does not permit such a printing.

Informed consent is a process that may require multiple discussions with patient by the clinical team. The informed consent must be made knowingly and given freely. The patient must be conscious and competent to understand the purpose and effect of the decision to be made and the form to be signed. The consent form itself is not informed consent; it is an adjunct to the documentation of the informed consent process in the medical records. The provider(s) involved in the consent process does not have to be present when the patient signs the iMed consent form.

The iMed informed consent program and associated printed form shall be used when informed consent is required. The iMed consent form will include the name of the practitioner performing the procedure and, if applicable, that other physicians or staff, including residents, will be performing tasks related to the procedure.

The time and date on the form should be the time and date the form is signed by the patient or the patient's legal representative, not the time and date of the procedure or operation.

The original signed iMed consent form shall be placed in the patient's medical record and a copy given to the patient.

When a person other than the patient signs the iMed consent form, the relationship to the patient should be noted.

If the patient's inability to sign is due to a temporary condition, informed consent from the patient should be attempted when the patient is able.

A consent remains effective until the patient revokes it or until circumstances materially change. In such a situation, informed consent would need to be re-obtained.

Consent should be obtained by telephone only if the person having the legal ability to consent for the patient is not otherwise available. If telephone consent is used, the physician must provide the patient's legal representative with all of the information the physician would disclose if the person were physically present. The iMed form shall also be used during telephone consent.

The physician or designee who performs the consent must utilize a qualified interpreter if the patient or legal representative is Limited English Proficient (LEP). The physician must also ensure that the Translator Attestation Form is completed.

If the patient or their legal representative is physically unable to write his or her name, the person's mark must be obtained. This is done by the physician first writing the person's name in full on the signature line, and then having the person place an "X" next to it.

If the patient is unable to write his name or make a mark, verbal consent is acceptable. The provider writes "verbal consent by_____ (name of patient) on the signature line"

This informed consent process does not require a witness. However, if the patient or provider prefers a witness to the informed consent discussion, the provider must document the name of the witness to the consent process in the patient's medical records.

The principles set forth in the California Hospital Association Consent Manual shall serve as guidelines for obtaining and documenting appropriate consent for medical treatment and/or procedure.

Attachment A: List of Procedures That Do Not Require Informed Consent and Time-Out Process

REFERENCES: DHS Policy # 318, Non-English and Limited English Proficiency
DHS Policy # 314, Informed Consents
California Hospital Association Consent Manual 2016

Approved: MEC O& EC 2016

CM 11/2014
CM/ SB/GS 11/17/16, 2019, 2021

Attachment A:

The following procedures are covered under "Conditions of Admissions Form" or General Consent form and therefore, do not require separate Informed Consent form and Time-Out Process.

LIST OF PROCEDURES THAT DO NOT REQUIRE INFORMED CONSENT FORM AND TIME-OUT PROCESS:

- **Wound Vacuum**
- **Toenail Cutting**
- **Callus Shaving**
- **Foley Catheter Insertion**
- **Nasogastric Tube Insertion**
- **Pap Smear**
- **Serial Casting**
- **Ear Cleaning**
- **Trach Change**
- **Cautery of Bleeding/Granulation**
- **Laryngoscopy**
- **Nasal Endoscopy**
- **Tracheoscopy (Tracheostomy requires Informed Consent; Tracheoscopy does not)**
- **Wound Debridement in Outpatient Setting**
- **Chronic Hemodialysis or Chronic Peritoneal Dialysis***

  * (First episode of dialysis or change in dialysis modality {e.g., formerly hemodialysis now converted to peritoneal, or visa-versa}, require separate written informed consent. Patients who are receiving chronic dialysis (whether hemodialysis or peritoneal) or who have received prior dialysis during the current hospitalization do not require a separate consent to receive additional dialysis sessions.)

- Orthopedic cast application with or without manipulation or fracture reduction
- Orthopedic injections (including joints, sheaths, bursae, nerve blocks, hematoma blocks, and trigger points)
- Flexible Endoscopic Evaluation of Swallowing (FEES)
- Videolaryngoscopy (VLS)