TAOS HEALTH SYSTEMS, INC.

SCOPE: Organization Wide
DEPARTMENT: Quality, Risk & Compliance
REVISED DATE: 2/18/2025
APPROVED BY: Misty Carruth, DQRC

Informed Consent

I. POLICY PURPOSE: To establish guidelines to ensure that patients receive and understand information needed to evaluate treatment options, risks and benefits in order to give informed consent.

II. POLICY STATEMENT: Every patient has the right to participate in an informed consent discussion. This means that the patient has the right to receive a complete explanation of the proposed medical/surgical treatment or procedure from his/her practitioner before deciding whether to consent to having the proposed medical/surgical treatment or procedure done. It is necessary that patient's informed consent be obtained prior to the medical/surgical treatment. In order to provide informed consent, the patient must understand the nature and purpose of the proposed medical/surgical treatment or procedure, the risks, the benefits, the alternatives, and the consequences of foregoing the proposed medical/surgical treatment or procedure. This is a process and the conversation should be documented as such in the patient's medical record along with the signed informed consent form.

III. PROCEDURE:

A. Consent Is Required For:

1. All invasive procedures, including major or minor surgery involving an entry into the body, either through an incision or through a natural body opening;

2. All high-risk therapies/drugs;

3. All procedures in which general/spinal anesthesia is used and certain procedures in which a local anesthetic is used;

4. Medical procedures that involve more than a slight risk of harm to the patient or which may cause a change in the patient's body, e.g., chemotherapy, diagnostic procedures involving contrast or dyes, administration of drugs that carry very serious or irreversible side effects;

5. Some forms of radiology therapy;

6. Experimental procedures and clinical trials;

7. Other procedures that the medical staff determines requires a specific explanation to the patient;

8. Blood and blood product use; or

9. Any off-label use of medical devices or medications if there is a potential for significant risk.

10. *Test for HIV (unless a healthcare practitioner has been exposed to the patient's bodily fluids inadvertently while caring for the patient or the patient's bodily fluids); *HIV testing does not require a signed informed consent form. Verbal Informed consent is documented in the medical record.

B. Who Must Give Consent:

1. Adult Patients:

a. The consent of every competent adult patient should be obtained prior to treatment. For purposes of consent, competency may be defined as an ability to understand the nature and consequences of the proposed medical/surgical treatment or procedure.

b. Unless otherwise provided in an advanced directive signed by the patient, in New Mexico, every adult patient is presumed to be competent to make a health care decision. A patient who appears to lack capacity to make such decision must be determined to be incompetent (i.e., lack capacity) by two qualified health professionals, one of whom should be the patient's primary care practitioner when feasible. If the patient is thought to be incompetent due to mental illness or developmental disability, a practitioner must be a person whose training and expertise aid in the assessment of functional impairment. If the patient challenges a finding of lack of capacity, the patient's wishes prevail unless otherwise orderd by a court.

c. If the patient is not capable of giving consent because of incompetence or other incapacity, consent should be obtained from a person who is empowered to act on the patient's behalf (e.g., patient advocate, legal guardian). If a guardian or patient advocate has been appointed, a copy of the guardianship, durable power of attorney or other authorizing document(s) needs to be included in the patient's medical record.

d. If the procedure is not a medical emergency, there is no one with the legal capacity to consent for the patient, and the attending practitioner determines that the patient is temporarily incapacitated, treatment should be withheld until the patient regains capacity. If the attending practitioner determines that the patient is permanently incapacitated or that it is medically

inadvisable to delay treatment until the patient regains capacity, approval should be sought from a member of the patient's immediate family. In the matter of life saving treatment and no family is available, the practitioner may make the decision supported by comprehensive medical decision-making documentation.

e. When needed, consent from a family member should be sought in the following order of priority, subject to availability and time constraints:

1) Spouse

2) Adult children

3) Parent

4) Adult siblings

5) Other close relative or significant other

2. Minor Patients: If patient is under the age of 18, then typically a parent, legal guardian, or person acting in loco parentis must sign the consent, except in the following situations.

a. When a minor is emancipated

b. A minor age 14 or over living apart from parents or legal guardians seeking medically necessary care

c. A minor who is a parent and seeking medically necessary care for their child

d. Treatment for substance use disorders

e. Treatment for sexually transmitted diseases

f. Contraceptive care

g. Prenatal care and treatment

h. Mental health care and treatment: minors age 14 or over must consent to treatment if competent to do so. However, parents must be given notice of any use of psychotropic drugs. The minor may consent to use of the drugs and consent to disclosure to the minor's parents or legal guardians in order to give required notice to the parents. If the minor refuses to consent to notice to parents, legal advice should be obtained prior to proceeding with treatment using

psychotropic drugs. A child under the age of 14 may consent to initial assessment and early intervention services, exclusively verbal therapy. Parents must give consent for further treatment after the initial assessment and early intervention.

3. Emergency Situations: When immediate treatment is required to preserve the life of a patient or to prevent an impairment of the patient's health and it is impossible to obtain the consent of the patient or other legally authorized individual, the hospital and its practitioners may render treatment that is necessary to preserve the patient's health until such time as the patient (or an authorized representative) can give any consent that is necessary. The practitioner must document in the medical record that an emergency exists and that immediate treatment is needed to preserve the life or prevent serious impairment to the patient's health.

4. Refusal to Consent: A competent adult patient has the right to refuse any medical or surgical procedure (including emergency lifesaving treatment). The patient will be informed of the consequences of the refusal. The patient's refusal should be noted on the medical record and a release should be secured from the patient (if possible) to document that treatment would have been rendered if the patient had not refused. Informed refusal should be documented with the same care and detail as informed consent.

5. Duration of Consent: Consent for a particular procedure, such as surgery, is generally effective until the procedure is performed (as long as the patient's condition does not change), but should not be obtained more than 30 days before the contemplated procedure. For patients undergoing repetitive treatment, such as infusion therapy or wound care, obtaining consent for the series of treatments over a specified time frame is acceptable. Obtain a new consent if there is a change in the patient's health status or the procedure and/or treatment that alters the risks and benefits, increases discomfort, or may result in side effects originally disclosed to the patient.

6. Methods of Consent:

    a. Written Consent: A properly signed consent form, obtained prior to treatment, is the most effective manner in which to prove a valid authorization for a medical/surgical procedure. The original of each consent form is kept in the patient's permanent medical record. The signature of the patient or patient representative should be provided freely and of his/her own accord, and witnessed by at least one staff person.

    b. Telephone Consent: Circumstances may be such that the consent of an authorized representative of the patient needs to be obtained over a telephone in order to avoid a delay in treatment. The telephone conversation should be noted on the consent form, indicating the

time and nature of the consent, and, if possible, the conversation should be witnessed by two persons on the same telephone line.

7. Responsibility:

   a. Practitioner Performing Procedure: Practitioners are responsible for providing the patient with appropriate information in terms and language that the patient understands – Describing the planned procedure includes, but is not limited to, the following:

      1) Diagnosis of illness being treated

      2) Nature/purpose of the proposed treatment

      3) The names of practitioners performing important aspects/significant surgical tasks of the procedure and the specific significant tasks they will perform

      4) Risks/consequences of treatment

      5) Benefits of the proposed treatment

      6) Feasible alternatives available

      7) Prognosis if no treatment is rendered

      8) Giving the patient the opportunity to ask questions and receive answers to the patient's satisfaction.

   b. Ensuring that all of above elements of the informed consent discussion are documented in the medical record as well as in an informed consent form

8. Registered Nurse and Radiology Radiology/Ultrasound Technologist: Registered Nurses and Radiology/UltrasoundTechnologists are responsible for the following:

   a. Providing the appropriate forms for the medical/surgical treatment or procedure and ensuring that the appropriate consent form is present in the medical record before the medical/surgical treatment or procedure is commenced.

   b. Reviewing the appropriate consent form and/or the supplemental documentation in the medical record: The following information must be included in the record:

      1) Patient identity

2) Diagnostic or therapeutic procedure/treatment

3) Name of individual performing procedure

4) The names of practitioners performing important aspects/significant surgical tasks of the procedure and the specific significant tasks they will perform

c. Coverage of the elements of a valid consent within practitioner discussion including:

1) Diagnosis

2) Nature/purpose of care to be provided

3) Other significantly participating practitioners

4) Risk/consequences of care

5) Feasible alternatives

6) Potential benefits

7) Prognosis if no treatment is rendered

8) Signature by person with capacity to consent

9) Patient/patient representative signature on form or appropriate documentation.

d. Being available to witness the patient's signature – The Registered Nurse or Radiology Radiology/Ultrasound Technologist is not responsible for securing the consent or ensuring that proper information was given to the patient or patient representative. However, immediately prior to having the patient sign the consent form, the non-practitioner healthcare provider should ask the patient the following questions:

1) Have you read the consent form?

2) Do you understand the consent form?

3) Do you have any questions?

e. Contacting the practitioner and appropriate department personnel if a signed consent form is not present in the medical record and/or the information listed in item 2 above is not evident in the medical record.

f. Referring any patient questions regarding the elements of informed consent to the practitioner responsible for obtaining informed consent, before allowing the patient to sign the consent form.

g. Delaying the procedure and/or having the patient sign the consent form until the practitioner responsible for obtaining informed consent has addressed all questions.

h. Contacting the appropriate supervisor or Administrator on Call (AOC) if the responsible practitioner refuses or fails to respond to the Registered Nurse. The supervisor or AOC will contact the appropriate service chief or chief-of-staff if further assistance is needed. The service chief or chief-of-staff is expected to respond in a timely manner to requests for assistance.

C. Miscellaneous

1. Signatures:

a. A legal signature is any mark intended to be a person's signature. All signatures on any documents should be in ink, including the signatures of a witness and any other information written on the document.

2. Witnesses:

a. Employees who have reached the age of majority may legally sign as a witness.

b. Employees will not become involved in the personal legal affairs of patients.

c. Surgical consents, permissions for autopsy, and various releases from responsibility may be witnessed by a Registered Nurse or by an employee of the practitioner who is at least 18 years of age. Nursing students should not act as a witness.

SOURCE REFERENCES:
Coverys Informed Consent Policy
Coverys Risk Management Helathcare Facility Manual. NMSA 24-7A-11; NMSA 24-7A-6.2; NMSA 32A-6A-14

APPROVAL CHART

Policy Category	Approvals needed	Signature/Date
Single department	Director/Manager	
Multiple Departments under same Director/Manager	Director/Manager	**8/27/2020: Leadership**
Multiple Departments under multiple Director/Managers	Director/Manager for each department	
Organization/Hospital-wide	Senior Leadership Team	**8/31/2020**
Medical Decision Making/Practitioner Responsibilities	□ Emergency Department □ Pediatric & Adult Medicine □ Surgery & Anesthesia □ Peri-natal □ MEC/Chief of Staff	**ED: 8/13/2020** **PAM: 9/08/2020** **SA: 8/25/2020** **Perinatal: 8/18/2020**
Medical Staff or Governing Board Responsibilities	□ MEC/Chief of Staff □ Governing Board	**MEC: 9/18/2020**
Effective Date:		**9/18/2020**
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