Defense Health Agency

ADMINISTRATIVE INSTRUCTION

NUMBER 6025.24
September 18, 2024

DAD-MA

SUBJECT: Informed Consent for Medical and Dental Treatments and Procedures

References: See Enclosure 1

1. PURPOSE. This Defense Health Agency-Administrative Instruction (DHA-AI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (q), establishes the Defense Health Agency's (DHA) procedures for obtaining informed consent required for a specific occurrence of a treatment, procedure, and/or therapeutic course of care. This DHA-AI does not address consent for human subjects' research or sexual assault forensic examinations of adults, adolescents, and minors.

2. APPLICABILITY. This DHA-AI applies to the DHA Enterprise (components and activities under the authority, direction, and control of DHA), to include assigned, attached, allotted, or detailed healthcare personnel who engage in the informed consent process for medical and dental treatments and procedures for all patients eligible for care at military medical and dental treatment facilities (MTFs/DTFs). This applies to all healthcare providers/practitioners and medical/dental teams working within MTFs/DTFs (hereinafter referred to as "DHA healthcare providers/practitioners").

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to References (a) through (p) that the guidance in these References establishes uniform accountability, standards, and processes for obtaining informed consent for medical and dental treatments and procedures for all patients eligible for care at MTFs/DTFs.

4. CANCELLED DOCUMENTS. This DHA-AI cancels the Assistant Director for Healthcare Administration Memorandum, "Minors and Reproductive Health Care Services (Overseas)," March 12, 2023.

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosure 3.

7. RELEASABILITY. **Cleared for public release**. This DHA-AI is available on the Internet from the DHA SharePoint site at: https://www.health.mil/Reference-Center/DHA-Publications and is also available to authorized users from the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/DHA%20Publications%20Signed/Forms/AllItems.aspx.

8. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director, Medical Affairs (DAD-MA). When components and activities are unable to comply with this publication the activity may request a waiver that must include a justification, including an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their Defense Health Network leadership to the DAD-MA to determine if the waiver may be granted by the Director, DHA or their designee.

9. EFFECTIVE DATE. This DHA-AI:

a. Is effective upon signature.

b. Will expire 5 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).

10. FORMS. The Optional Form (OF) 522, Request for Administration of Anesthesia and for Performance of Operations and Other Procedures (DoD Exception approved by GSA) is available at: https://info.health.mil/cos/admin/DHA_Forms_Management/Lists/DHA%20Forms%20Management/AllItems.aspx.

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TELITA CROSLAND
LTG, USA
Director

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ENCLOSURE 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013, as amended
(c) DHA-Procedural Instruction 5025.01, "Publication System," April 1, 2022
(d) United States Code, Title 10, Section 1073c
(e) DoD Instruction 6000.14, "DoD Patient Bill of Rights and Responsibilities in the Military Health System (MHS)," April 3, 2020, as amended
(f) DHA-Procedural Instruction 6025.10, "Standard Processes, Guidelines, and Responsibilities of the DoD Patient Bill of Rights and Responsibilities in the Military Health System (MHS) Military Medical Treatment Facilities (MTFs)," October 9, 2018, as mended
(g) Joint Commission for the Accreditation of Healthcare Organizations Accreditation Manual for Hospitals, latest edition
(h) DHA-Administrative Instruction 5010.01, "Forms Management Program," January 12, 2021, as amended
(i) DoD Instruction 6025.27, "Medical Ethics in the Military Health System," November 8, 2017
(j) DHA Procedural Instruction 6025.39, "Medical Ethics in the Military Health System," August 20, 2021
(k) DHA Procedural Instruction 6025.17, "Healthcare Resolutions, Disclosure, Clinical Conflict Management and Healthcare Provider (HCP) Resiliency and Support in the Military Health System (MHS)," June 18, 2019
(l) Army Regulation 600-20, "Army Command Policy," Chapter 5, July 24, 2020
(m) Manual of the Medical Department (MANMED), NAVMED P-117, Paragraph 2-18
(n) DHA Administrative Instruction 6025.09, "Walk-in Contraception Services at Military Medical Treatment Facilities," September 27, 2022, as amended
(o) DHA-Procedural Instruction 6200.02, "Comprehensive Contraceptive Counseling and Access to the Full Range of Methods of Contraception," May 13, 2019
(p) American Medical Association, Code of Medical Ethics, Consent, Communication and Decision Making, "Informed Consent," December 20, 2023
(q) DHA-Policy Memorandum 23-010, "Parental Access to Protected Health Information of Unemancipated Minors," October 5, 2023

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA will:

a. Support the establishment of guidance, procedures, and direction for obtaining informed consent for medical and dental treatments and procedures.

b. Ensure Defense Health Networks and their reporting MTFs/DTFs implement informed consent guidance for medical and dental treatments and procedures provided at those locations, as outlined in this DHA-AI.

c. Assign responsibility for tracking compliance with the standard procedures and criteria outlined in this DHA-AI to the DAD-MA.

2. DAD, HEALTH CARE OPERATIONS. The DAD, Health Care Operations, will establish, direct implementation of, and ensure compliance with standards and procedures for informed consent in medical and dental records as directed in this DHA-AI.

3. DAD-MA. The DAD-MA will:

a. Ensure implementation of the requirements of informed consent practices established by this DHA-AI within the MTFs/DTFs.

b. Ensure MTF/DTF healthcare personnel have, and are aware of, the tools, processes, resources, capabilities, and procedures for addressing ethical and legal issues associated with informed consent; including access to medical ethics training, and high-quality, medical, ethical, and legal consultation services consistent with the procedures set forth in this DHA-AI.

c. Support Defense Health Networks and MTFs/DTFs by identifying and implementing standard clinical, business, and administrative process changes procedures.

d. Reduce variation in the informed consent process and monitor and track informed consent performance metrics across MTFs/DTFs.

e. Propose updates to this instruction as necessary with respect to informed consent procedures in support of continuous process improvement.

f. Track compliance with the standard procedures and criteria outlined in this DHA-AI.

4. CHIEF INFORMATION OFFICER/J6. The Chief Information Officer/J6 will:

a. Allow for flexibility in the platform and format (paper and pencil) used for informed consent as there is variability in the electronic platform (i.e., Armed Forces Health Longitudinal Technology Application (ALTHA), Essentris, MHS GENESIS) used for informed consent across MTFs/DTFs.

b. Assist in initial implementation and maintenance of the platform used to manage electronic informed consent documents within MHS GENESIS.

c. Provide the technical framework to sustain an information technology (IT) infrastructure for the platform used for electronic informed consent documentation and forms that enable collaboration and the ability to share information.

5. DIRECTORS, DEFENSE HEALTH NETWORKS. The Directors, Defense Health Networks will:

a. In collaboration with aligned legal counsel, verify MTFs/DTFs informed consent guidance sufficiently addresses treatments and procedures performed in the organization as outlined in this DHA-AI.

b. Implement and manage requirements for the utilization of informed consent within the MTFs/DTFs and other DHA entities as outlined in this DHA-AI.

c. Track and monitor MTF/DTF standardization and compliance with the informed consent process as outlined in this DHA-AI.

d. Implement and monitor specific informed consent educational and training activities in accordance with this DHA-AI.

e. Submit quarterly reports on informed consent performance metrics, to include educational and training activities to DAD-MA.

f. Ensure informed consent education and training is provided for Network MTF/DTF healthcare personnel in accordance with this DHA- AI.

g. Ensure MTF Directors develop processes for the management, utilization, and coordination of informed consent that aligns with this DHA-AI and future DHA recommendations and guidance.

6. DIRECTORS, MTFs. MTF Directors will:

a. Implement this DHA-AI and any Defense Health Network guidance and procedures for the informed consent process at their MTFs/DTFs.

b. Ensure that local MTF/DTF guidance aligns with applicable laws and regulations and

clearly identifies what procedures a legally authorized representative (LAR) decision maker may not consent to.

c. Ensure that DHA healthcare providers/practitioners have the education and training to adequately explain risks, benefits, and alternatives to the patient or LAR in accordance with applicable state laws and Department of Defense (DoD) policy.

d. Provide a method for DHA healthcare providers/practitioners in the MTF/DTF to obtain information about informed consent and have access to answers to specific questions, including, but not limited to, the extent of disclosures and requirements for the use of written consent.

e. Consistent with References (e) and (f) and as required by Reference (g), as applicable create and post MTF/DTF guidance on informed consent on facility SharePoint site for DHA healthcare providers/practitioners to access and to reference as needed.

f. Ensure all consent forms used comply with DHA Forms Management guidance, Reference (h).

7. DHA HEALTHCARE LICENSED INDEPENDENT PROVIDERS/PRACTITIONERS PRACTICING IN MTFs/DTFs. DHA healthcare licensed independent providers/practitioners practicing in MTFs/DTFs who are responsible for the patient's care will:

a. Inform patients, or if the patient is incapable of making medical or dental decisions, the LAR, of the risks, benefits, and alternatives of the proposed treatments and procedures consistent with this DHA-AI and applicable standards of care.

b. Adhere to the procedures and requirements for informed consent as outlined in this DHA-AI and the applicable Defense Health Network and local (i.e., MTF/DTF) informed consent guidance.

c. Attend appropriate training to familiarize and adhere to the requirements of the informed consent instruction and applicable law for their Defense Health Network and MTF/DTF.

d. Document in the patient's electronic health record (EHR) that the informed consent discussion occurred. When written consent is required, include the signed Defense Health Network/MTF/DTF approved informed consent form in the patient record. In the absence of a Defense Health Network/MTF/DTF approved informed consent form, the OF-522 form, Request for Administration of Anesthesia and for Performance of Operations and other Procedures (DoD Exception approved by GSA) may be used.

e. Consult References (i) and (j) for additional guidance regarding medical ethics as it relates to questions or issues in this issuance. Work with the Chief, MTF/DTF Healthcare Ethics Committee to address the questions before submitting consults, as needed, to the Defense Medical Ethics Committee to request guidance on addressing their healthcare ethics questions, concerns, and dilemmas.

8. HEALTHCARE PERSONNEL. Healthcare personnel who are members of the treatment team will assist the responsible licensed independent DHA healthcare provider/practitioner when questions regarding the patient's capability of making medical or dental care decisions arise.

9. CHAIR, MTF/DTF HEALTHCARE ETHICS COMMITTEE. Under the direction of the Chief, MTF/DTF Healthcare Ethics Committee, the Committee will assist as necessary with ethics questions and will provide guidance regarding ethics questions and matters regarding healthcare informed consent.

10. SERVICING DHA LEGAL OFFICE OR ADVISOR. Under the direction of the Chief, Office of General Counsel, the MTF's servicing DHA Legal Office or legal advisor will:

a. Serve as a resource for DHA healthcare providers/practitioners who have questions about applicable regulations and laws regarding informed consent requirements.

b. Review local policies regarding informed consent to ensure compliance with applicable regulations and laws.

c. Give legal guidance and provide training, when requested, on informed consent based on statutory, regulatory, or policy requirements to DHA healthcare providers/practitioners and clinical teams.

11. HEALTHCARE RESOLUTIONS SPECIALIST. The Healthcare Resolutions specialist assisting the MTF will provide support consistent with Reference (k).

ENCLOSURE 3

PROCEDURES

1. OVERVIEW. Informed consent is a process to ensure that the patient has sufficient information, in terms that the patient can understand, to make an informed decision about their medical and dental treatment plan and procedures. Informed consent focuses on the nature and quality of the consent, imposing a duty of care on providers to disclose to a patient all information material to their health care decisions.

2. PATIENT RIGHTS AND RESPONSIBILITIES. Patients have the right to information in plain language, that is easily understood, and given in non-clinical terms to ensure that patients can make knowledgeable decisions about consent or refusal for treatments and procedures as applicable.

a. The term "consent" in the healthcare setting refers to a patient's agreement to undergo medical and dental treatments and procedures.

b. Patients have the right to accept or refuse any medical and dental treatments and procedures recommended to them. Except as otherwise provided by emergency or exemption, all treatments and procedures require the prior, voluntary informed consent of the patient, or if the patient lacks decision-making capacity, the patient's LAR. The term "LAR" refers to any individual person, judicial body or other body of individuals who is legally authorized under applicable law and policy to give informed consent to medical or dental treatment on behalf of a designated person when that individual lacks capacity to make decisions.

c. For patients who have decision-making capacity, the informed consent process will proceed as outlined below in Paragraph 3, Patient Informed Consent Process.

d. If the patient is considered a minor under applicable law in the jurisdiction where the DHA MTF/DTF is located and cannot consent for the treatment or procedure under applicable law, that patient is deemed to lack decision-making capacity. Consent must be obtained from the patient's parent or LAR. See Paragraph 9, Special Circumstances for Care of Minors, for additional information. Additionally, for patients who have been ruled incompetent by a court of law, consent must be obtained by a LAR. In instances where an adult patient has not been ruled incompetent by a court of law, but there is concern that the patient may lack capacity to consent, follow Paragraph 4 before obtaining consent.

e. When a patient or LAR has capacity to consent but is unable to hear, read, write, or understand English, MTF/DTF staff must make appropriate accommodations for medical/dental translation services or medical/dental interpreter per References (e) and (f). Family members should not serve in the role of medical translators.

3. PATIENT INFORMED CONSENT PROCESS. During the informed consent process, the DHA healthcare provider/practitioner must engage the patient or LAR in a discussion about treatments and procedures using plain language. Agreement by a patient/LAR who does not comprehend treatment options is not informed consent. The process of informed consent recognizes and respects patient autonomy in medical or dental decision-making. Ideally, the informed consent discussion is conducted in person; however, face-to-face discussions are not always possible. In order to take into account patient preferences, issues with access to care and concerns about infection control, the informed consent discussion may be conducted by telephone, video conference, or another DHA-approved electronic modality. DHA healthcare providers/practitioners should cover the following topics during the informed consent discussion:

a. Provide information for a patient (or LAR if the patient lacks decision-making capacity) to make an informed choice about whether to undergo medical and dental treatments and procedures.

(1) In accordance with Reference (g), DHA healthcare providers/practitioners will include in the informed consent discussion the name and details of the patient's proposed treatment, or procedure; potential benefits, risks, and side effects of the patient's proposed treatment or procedure, and the likelihood of the patient achieving their treatment goals. The risks and benefits of not receiving the proposed treatment or procedure, and any potential problems that might occur during recuperation should also be included in the informed consent discussion.

(2) There are specific requirements for obtaining and documenting informed consent when individuals in training, other than the operating licensed independent provider/practitioner, perform important tasks related to the surgery or examinations or invasive procedures for educational and training purposes in sensitive areas (such as breast, pelvic, prostate, and rectal examinations), particularly on anesthetized or unconscious patients. See Paragraph 5c. Without obtaining and documenting the consent, these learners may NOT perform any sensitive examinations of patients under anesthesia unless there is a medical emergency necessitating such an exam.

(3) The DHA healthcare provider/practitioner may delegate the responsibility of reviewing detailed informed consent information with a patient or LAR to other trained personnel but must personally verify with the patient or LAR that they have been appropriately informed and voluntarily consent to the medical and dental treatments and procedures. However, the attending DHA healthcare provider/practitioner retains the responsibility to obtain informed consent from the patient or LAR.

b. For clinical and diagnostic tests that provide extremely sensitive information or that may have a high risk of significant consequences (e.g., physical, social, psychological, legal, or economic) that a patient might want to consider, the informed consent discussion must include information that a reasonable person in the patient's situation would expect to receive in order to make an informed choice.

c. Provide a clear and concise explanation of the patient's diagnosis(es) or condition(s) that relates to the recommended medical and dental treatments and procedures.

d. Risks of minor harm do not have to be described unless they commonly occur. Risks that are extremely unlikely do not have to be described, unless the patient requests that information, or unless such risks may result in serious injury, death, or permanent disability.

e. Describe reasonable alternative treatments and procedures. The DHA healthcare provider/practitioner must:

(1) Explain why the recommended treatments and procedures are thought to be more beneficial to the patient than the alternative(s).

(2) Describe any expected benefits, likelihood of success, and known risks associated with alternative treatments and procedures.

(3) Include in the discussion the material risks of refusing all treatments and procedures and the relevant risks, benefits, and side effects related to alternatives.

(4) Discuss the option of no treatment or procedure and the expected benefits and known risks of that option; and

(5) Explain that when treatment alternatives, particularly "no treatment" alternative, is chosen that the selection of an alternative in this instance does not impair the patient's right to treatment for other conditions.

(6) Include in the discussion that potential emergency responses to known complications of a treatment or procedure that the patient may wish to forgo (e.g., blood transfusion for bleeding during an operation, hysterectomy for complications of an obstetrical procedure, open heart surgery for complication of an angioplasty).

f. The alternatives offered and the patient's choice must be properly documented in accordance with Paragraph 5 below.

4. DETERMINATION OF DECISION-MAKING CAPACITY

a. In order to obtain informed consent, DHA healthcare providers/practitioners must first determine whether the patient has decision-making capacity. While patients are presumed to have decision-making capacity, there are instances where there is a concern that this is not the case. In those situations, the DHA healthcare provider/practitioner will conduct an appropriate clinical evaluation or assessment to determine if the patient lacks decision-making capacity and document it in the patient's records. Factual incompetence (or lack of "capacity") is based on a medical determination concerning the patient's cognitive ability to make informed decisions. Legal incompetence is established by operation of law, such as a statute concerning age, or by judicial decree concerning mental status. Patients who have been judicially determined to be

incompetent are incapable of giving consent as a matter of law. Such persons are deemed to lack decision-making capacity for the purpose of giving informed consent.

b. If the patient is likely to regain decision-making capacity, the provider must wait to perform the recommended procedure or treatment until the patient has the capacity to make the informed consent decision, unless delaying it would adversely affect the patient.

c. If the DHA healthcare provider/practitioner determines that the patient is unlikely to regain decision-making capacity within a reasonable period of time, or the DHA healthcare provider/practitioner determines that delaying the treatment would adversely affect the patient's life or health, informed consent from an authorized LAR should be sought.

d. If a patient lacks decision-making capacity and does not have an appointed healthcare agent, a court-appointed guardian may consent for medical or dental decisions. The court-issued letters of guardianship should identify whether, and with what limitations, the court-appointed guardian has authority to consent to proposed medical or dental decisions of the ward. A copy of the court order will be included in the EHR.

e. If there is no appointed agent and no court-appointed guardian, follow applicable law to determine the order of precedence for consenting an alternate (surrogate) decision-maker. This hierarchical scheme usually involves spouses (and in certain jurisdictions domestic partners), parents, siblings, and other relatives. Consult with servicing legal counsel as needed.

f. In some jurisdictions, friends who maintain regular contact with the patient sufficient to be familiar with the patient's activities, health, and personal beliefs may be allowed to consent after signing an affidavit attesting to this relationship. If permitted, the affidavit must be included in the patient's EHR. Consult with servicing legal counsel as needed.

g. When the determination of lack of decision-making capacity is based on a diagnosis of mental illness:

(1) A behavioral health licensed independent provider/practitioner credentialed to conduct competence evaluations must be consulted to ensure that the underlying cause of the lack of decision-making capacity is adequately addressed. See Section 10, Special Consideration for Consent for Treatment of Patients with a Mental Health Disorder, for additional information.

(2) The DHA healthcare provider/practitioner who will be performing the treatment or procedure remains responsible for the final determination of decision-making capacity with respect to informed consent for that treatment or procedure.

h. Questions concerning consent requirements, conflicts with the law, or authority to consent will be referred to the MTF/DTF's servicing DHA legal advisor. These instances may include, but may not be limited to, when the responsible DHA healthcare provider/practitioner knows that the patient has previously expressed disagreement with the proposed treatment, when there is a disagreement among potential LARs, or disagreement between intended treatment and an

advanced directive. As appropriate, the Healthcare Ethics Committee or Healthcare Resolutions can provide support for the DHA healthcare provider/practitioner.

i. If a DHA health care provider/practitioner believes that a patient who has been judicially determined to be incompetent does in fact have the capacity to make a particular health care decision, the DHA healthcare provider/practitioner should discuss this with the court-appointed guardian.

5. DOCUMENTING THE INFORMED CONSENT PROCESS

a. General Provisions.

(1) DHA recognizes "general" consent for medical and dental treatments and procedures. General consent often includes general consent for examination and procedures associated with evaluation and diagnostics such as laboratory tests and imaging. However, written consent is required for each specific occurrence of invasive treatment, procedure and therapeutic course of care that has a reasonable possibility of causing significant physical or emotional harm.

(2) If the original informed consent encompasses treatments and procedures (to include multiple or recurrent treatment or procedures) to be performed and if there is no material change to the patient's conditions, it is generally not necessary to repeat the informed consent discussion for each new treatment or procedure.

(3) There are two circumstances where the informed consent discussion, and the Defense Health Network/MTF/DTF approved informed consent form, or in the absence of a Defense Health Network/MTF approved consent form, the OF-522, Request for Administration of Anesthesia and for Performance of Operations and Other Procedures (DoD Exception approved by GSA) is repeated and a new written consent form must be obtained:

(a) If there is a significant deviation from the treatment plan to which the patient originally consented; or

(b) If there is a change in the patient's diagnosis or condition that would reasonably be expected to alter the original informed consent.

(4) Off-label use of drugs, tissues, or devices as well as any provider conflicts of interest will be disclosed and documented.

b. Documentation of Treatments and Procedures that Require Written Consent.

(1) Prior to undertaking any treatments or procedures, the DHA healthcare provider/practitioner must obtain informed consent. The informed consent process will also be documented in the patient's EHR.

(2) If not contrary to federal law and DoD policy, DHA healthcare providers/practitioners should also follow state law that may require written informed consent for certain procedures and treatments. In the absence of state law having such a requirement, DHA healthcare providers/practitioners should obtain written informed consent and document the process as outlined in this instruction.

(3) When obtaining written consent and documentation of the informed consent process, the DHA healthcare provider/practitioner should obtain the patient's signature on either a Defense Health Network/MTF/DTF approved informed consent form or the OF-522 can be used in the absence of a Defense Health Network/MTF/DTF approved informed consent form. The exception to the requirement to obtain written consent can occur in the case where low risk dental procedures include local anesthesia. For all other treatments and procedures, written consent should be obtained if the DHA healthcare provider/practitioner determines that it:

(a) Can be reasonably expected to produce significant pain or discomfort to the patient;

(b) Can be reasonably expected to produce pain or discomfort to the patient that is substantial enough to require sedation or anesthesia. For dental procedures that include local anesthesia, written consent is not required.

(c) Can be invasive, have a significant risk of complication, or morbidity (i.e., other than low risk).

(4) Separate and specific signed informed consent is required if one is transfusing blood, administering anesthesia, and/or performing surgery. This does not include local anesthesia for dental procedures. A Defense Health Network/MTF/DTF approved informed consent form will be used for blood transfusions, anesthesia, and surgery. In the absence of a Defense Health Network/MTF/DTF approved informed consent form, a separate OF-522 must be used for each of the aforementioned procedures.

(5) Document the date and time the patient provided written consent for the treatment or procedure on the consent form used. The written or valid electronic signature of the patient or the patient's authorized LAR and the written or valid electronic signature of the practitioner writing the note (including the practitioner's legal written name) is required. The need for a witness signature on the form will be determined in accordance with applicable state law (when not in conflict with federal law and DoD policy) and local MTF/DTF or Defense Health Network-based consent policies.

(6) For the procedures requiring written consent, the OF-522 can be used in the absence of a Defense Health Network/MTF/DTF approved consent form to ensure the best patient safety practices have been utilized.

(7) Additional educational materials from professional organizations and federal agencies (e.g., Food and Drug Administration) may be included in the informed consent

process and documentation, but their use does not replace the need to use Defense Health Network/MTF/DTF approved consent forms or an OF-522.

(8) In circumstances where the patient or LAR is unable to sign the consent form due to a physical impairment, the patient or LAR may place an "X", thumbprint, or stamp in the "Signature" block on the consent form or designate a third party (not including the practitioner who is obtaining the informed consent) to sign the consent form on behalf of the patient or LAR.

(9) If a patient or LAR designates another individual to physically sign the form, this third party must sign the consent form in the presence of the patient or LAR. Two adult witnesses (excluding the treating or operating provider or designee obtaining consent) must witness when the patient or LAR places an "X", thumbprint, or stamp on the consent form or witness when a third-party sign the consent form on behalf of the patient or LAR, and both witnesses must sign the consent form.

c. Documentation of Written Informed Consent Involving Treatments or Procedures of Sensitive Areas.

(1) All medical personnel, including learners who perform sensitive examinations (such as breast, pelvic, prostate, and rectal examinations) outside the medically necessary procedures, need to obtain informed consent from the patient and properly document it in the patient's electronic health record (References (e), (f)). The term "learners" includes, but is not limited to residents, medical students, advanced practice providers (such as nurse practitioners and physician assistants) students, and other applicable trainees. As such, for procedures where learners may perform sensitive exam(s) under anesthesia, outside a medical emergency necessitating such an exam, the written consent form must include provisions outlined below.

(2) Residents and/or students, based on their skill set and under the supervision of the responsible practitioner, will be assisting with the surgical procedure under the direction of [name of supervising physician/clinician]. As part of assisting with the procedure, the residents and/or student may perform the following examinations:

(a) breast

(b) rectal

(c) prostate

(d) pelvic

(e) bladder catheter placement

(f) other

(3) This list may be truncated to only include the pertinent areas. For example, the consent form for a breast surgery could state "Residents and/or students will be assisting with

the surgical procedure under the direction of [name of supervising physician/clinician]. As part of assisting with the procedure, the residents and/or student may examine your breast." If qualified medical practitioners who are not physicians will perform important parts of the surgery or administration of anesthesia staff, add a statement that they will do so and that they will be performing tasks within their scope of practice and for which they have been granted privileges by the hospital.

(4) If there is an applicable standard in the community with respect to obtaining and documenting informed consent form for these procedures, incorporate those provisions. If there is not, a properly executed informed consent form contains the following minimum elements:

(a) Name of the hospital where the procedure/ medical treatment is to take place.

(b) Name of the specific procedure, or other type of medical treatment for which consent is being given.

(c) Name of the responsible practitioner who is performing the procedure or administering the medical treatment. Staff are also encouraged to document the name of the practitioner who conducted the informed consent discussion.

(d) Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative. (Material risks could include risks with a high degree of likelihood, but a low degree of severity, as well as those with a very low degree of likelihood, but a high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits, and alternatives will be discussed with the patient.)

(e) The date, time, and signature of the patient or the patient's legal representative, as well as the date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.

(5) Without the above consent, learners may NOT perform any sensitive examinations of patients under anesthesia unless there is a medical emergency necessitating such an exam.

d. Documentation of Treatments and Procedures Requiring Only Oral Informed Consent.

(1) Treatments and procedures that are low risk and within broadly accepted standards of medical practice and/or dental procedures that include local anesthesia allow for the use of oral informed consent.

(2) In the case of oral consent, orders placed in the patient's EHR by the provider are sufficient documentation for routine treatment and/or diagnostic care.

(3) Under rare/unusual circumstances it may be necessary to obtain oral informed consent over the telephone from a LAR on behalf of the patient. In those situations, staff must

follow the following procedures to properly document consent:

(a) Take reasonable steps to ensure the identification of the individual who is authorized to consent. This could include asking the person for information about the patient that only an individual close to the patient would know (e.g., asking a parent for a child's birth date).

(b) Include a third person who can monitor the telephone call.

(c) Outline all the information required to obtain informed consent with the person giving the consent. Answer all questions as fully as possible.

(d) Oral consent obtained over the telephone must also be documented in the EHR in a progress note. This entry should include a summary of all information provided by the provider/practitioner, questions by the person granting consent, a summary of the providers answers, and the name of the third person who monitored the telephone call. The person who monitored this conversation should also sign the entry in the EHR as a witness.

6. PATIENT SELECTION OF AN ALTERNATIVE TREATMENT OR PROCEDURE, THE NO TREATMENT OPTION, OR REVOCATION OF CONSENT

a. When the patient has the capacity to give consent, the patient may choose among recommended or alternative treatments and procedures that are consistent with accepted professional standards, including no treatment.

b. When the patient has the capacity to give consent, the patient may revoke a prior consent without prejudice to the patient's access to future health care or other benefits, even if that decision may increase the risk of serious illness or death.

c. If the patient chooses an alternative treatment or procedure, including no treatment, that increases the risk of illness or death, or revokes a prior consent, the progress note in the EHR must document the patient's reason(s), if known. Any effort to support the patient, the use of shared decision making, and expected outcomes should also be documented.

d. Whenever a patient (or LAR on behalf of a patient) revokes a prior consent, the responsible DHA healthcare provider/practitioner must:

(1) Write an addendum to the progress note associated with the prior informed consent.

(2) Ensure that the addendum states that the patient revoked the informed consent and document the date of the revocation.

(3) Ensure the note describes the substance of the discussion with the patient and

the reasons for the revocation.

(4) Take reasonable steps to ensure the revocation is noted in the EHR so that any additional or subsequent providers are apprised.

7. DURATION OF SIGNED CONSENT

a. Consistent with applicable law, any documentation concerning written consent is valid if there is no material change in circumstances between the date the patient/LAR signed the paperwork and the date of the treatments or procedures.

b. A new document is necessary if there is material change that has occurred in the patient's condition or a change in the treatments or procedures or the attendant risks, benefits, or alternatives to such treatments or procedures.

8. WHEN INFORMED CONSENT IS NOT REQUIRED

a. Emergency Medical Exception.

(1) A responsible DHA healthcare provider/practitioner may treat a patient—adult or minor—in an emergency, without consent, if certain elements are met.

(2) In the absence of an applicable law that sets out the required elements under the emergency medical exception, the typical required elements under the emergency medical exception include:

(a) The patient is unconscious or incapable of making an informed decision;

(b) The treatment or procedure is of an emergency medical nature, using the definition in applicable law (such as the law of the state where the MTF is located, when not in conflict with federal law and DoD policy), typically involving immediate threat to life, limb, or eyesight;

(c) A person who is authorized to give the consent is not available immediately (unless applicable law requires the provider to attempt to obtain consent from a relative, if time permits); and

(d) The attending DHA healthcare provider/practitioner determines there is a substantial risk of death or immediate and serious harm to the patient and with a reasonable degree of medical certainty, the life, limb, eyesight, or health of the patient would be adversely affected by waiting to obtain consent.

(3) When consent is not obtained due to an emergency medical situation, the responsible DHA healthcare provider/practitioner must document:

(a) The existence and scope of the emergency.

(b) The reason why consent was not obtainable, and if required by applicable law, what efforts were made to obtain consent from someone other than the patient. If the emergency condition is the result of compliance with a valid advance medical directive (AMD), document the circumstances and ensure that the AMD is included in the EHR.

(4) In cases where delay would not significantly increase the risk of harm, even though future medical or dental treatment will be necessary, informed consent must be obtained.

b. Therapeutic Privilege (see definition in Glossary). Before a provider withholds information from a patient on the basis that disclosing the information would inflict harm or suffering upon the patient, the provider must verify that this very limited privilege is recognized in the applicable jurisdiction; the MTF's servicing DHA Legal Office should assist in determining the applicability of the therapeutic privilege to meet the patient's needs. Consultation with the MTF Ethics Committee and/or Defense Medical Ethics Committee may be appropriate. The responsible DHA healthcare provider/practitioner must clearly document in the medical record the rationale for asserting this exception and include the nature and type of any consultation, family discussions, or other actions taken. Both the responsible DHA healthcare provider/practitioner and any consulting DHA healthcare provider/practitioner must sign the entry. The DHA healthcare provider/practitioner will include in the EHR a copy of any written ethics consultations.

c. Patient Request Not to be Informed. When a patient specifically requests not to be informed of the material risks of a proposed treatment or procedure, disclosure of those risks is not required. In such situations, the responsible DHA healthcare provider/practitioner must adequately document the reason the patient requested not to be informed of the material risks. If the DHA healthcare provider/practitioner has ethical or moral concerns regarding patient requests or declinations, an Ethics Committee consultation is appropriate.

d. Unanticipated Conditions Arising During Surgery. When a DHA healthcare provider/practitioner encounters unanticipated conditions during surgery, the surgeon can exercise reasonable judgment to treat an unanticipated condition that requires immediate action so that the patient's life or health is preserved. A Defense Health Network/MTF/DTF approved informed consent can be used and should include language addressing this exception such as "and any indicated procedures."

e. Exceptions to Consent for Service Members. DHA healthcare providers/practitioners will need to consider the provisions in Military Department policies, such as References (l) and (m), when military personnel in the Army and Navy, as patients, wish to refuse consent for treatment. Consults with servicing DHA Legal Offices or ethics committees may be needed given the particular circumstances.

(1) The provisions in References (l) and (m) generally grant medical officers the authority to take specific measures without a Service member's consent for the Army and Navy in certain limited circumstances.

(2) A medical officer generally has authority to provide emergency care when it is necessary to preserve the life or health of the Service member in an emergency, when obtaining informed consent in a timely manner is not practicable or when the member is determined mentally incompetent by a privileged mental health provider.

(3) A military commander may, in some circumstances, order a Service member under their command to submit to medical treatment, per References (l) and (m). The military's interest in requiring a member to accept treatment is limited to those circumstances where it is reasonably expected that the treatment will allow the member to return to full duty. In all other circumstances, the member should be afforded the same autonomy as any non- Active-Duty patient. Military personnel who refuse treatment should be advised of potential consequences regarding disability rights and benefits under applicable Service regulations and the impact that refusal of medical treatment will have on their continued ability to remain in the service.

(4) A Service member's refusal to be vaccinated is normally resolved through military disciplinary proceedings or administrative action by the Service member's unit. In rare instances, high-level officials may have the authority to require certain vaccinations regardless of the Service member's consent, such as in References (l) and (m). MTF staff should consult with their servicing DHA Legal Offices should mandatory vaccinations be required to ensure that leadership and those involved with providing the vaccinations are aware of what actions may or may not be taken to enforce the vaccination order in accordance with any applicable law, regulation, or policy.

9. SPECIAL CIRCUMSTANCES FOR CARE OF MINORS

a. Applicable laws vary with respect to consent for medical and dental treatment and procedures for minors, including the definition of a minor.

b. Once a patient becomes legally emancipated, she/he has the same capacity as an adult to consent to medical treatment. Applicable laws may determine one or more of the following factors emancipate the minor:

(1) Marriage

(2) Court order

(3) Enlistment in the military

(4) The type of treatment or procedure recommended or proposed or medical counseling for certain conditions

c. Some states recognize that a healthcare provider/practitioner may obtain informed consent from a "mature minor" who is sufficiently mature to understand the seriousness of his or her medical condition and the risks and benefits of treatment where the consent of the minor is sufficient to provide treatment. If, in the opinion of the responsible DHA healthcare provider/practitioner, a "mature minor" patient is able to fully understand the implications of the treatment or procedure and validly consent, the minor may assent and sign the Defense Health Network/MTF/DTF approved informed consent form or the OF-522 in the absence of a Defense Health Network/MTF/DTF approved consent form in addition to the parent, guardian, agent, or person providing informal kinship. Many states also permit minors being treated for sexual assault or child abuse to consent to certain treatment procedures related to the assault or abuse, and in some instances without the need to notify parents. DHA healthcare providers/practitioners can consult with the servicing DHA Legal Office for guidance and to address questions they may have about applicable laws.

d. Minors who arrive at the MTF/DTF for treatment and indicate that they reside/live apart from parents or LAR (i.e., state that they are "emancipated") present unique cases; contact the servicing DHA Legal Office for assistance.

e. Even when a minor may lawfully consent on their own, DHA healthcare providers/practitioners should make a sincere effort to encourage the minor to discuss the desired medical or dental care with the minor's parents or LAR or permit the DHA healthcare provider/practitioner to inform a parent or trusted adult, when, in the DHA healthcare provider/practitioners' professional judgement:

(1) Severe complications are present or are anticipated;

(2) Major surgery or prolonged hospitalization is anticipated;

(3) Failure to notify would jeopardize the safety and health of the minor patient; or

(4) Notification would benefit the minor's physical and/or mental health and impact support systems.

f. If the patient is considered a minor under applicable law in the jurisdiction where the DHA MTF/DTF facility is located, that patient is deemed to lack decision-making capacity for giving informed consent except as otherwise provided by law. Consent must be obtained from the patient's parent or LAR using the following process for obtaining consent for the outpatient treatment of minors:

(1) If a non-parental LAR has been court-appointed for a minor, the court-issued documentation should identify whether, and with what limitations the LAR has the authority to consent to proposed medical treatment or procedure of the ward. Unless otherwise specified, LARs usually have the same authority as parents to consent to non-surgical treatments or procedures of their wards. A copy of the order must be included in the minor's EHR.

(2) If the minor presents for treatment or procedure with a parent or LAR, that individual will consent for treatment. Absent a court decree or judgment stating otherwise, either parent may consent to treatment. In cases of a legal separation or divorce, most states require consent by the parent who has been granted legal custody of the child.

(3) When unavailable, the parent or LAR may give written authorization allowing the person in whose care, custody, or possession the minor has been placed to consent to treatments procedures for the minor. This authority may be granted in a medical care power of attorney and must be current and validly executed (e.g., signed, witnessed, and/or notarized per applicable State or Federal law).

(4) Absent this type of written authority, stepparents who have not adopted a stepchild have no authority to consent to medical treatments or procedures for a stepchild. The same rule applies to grandparents as with stepparents. The authority of a person in the process of adopting a child, or of a foster parent, to consent to treatments or procedures for a child is governed by applicable law and may depend on the type of treatment or procedure involved. In the case of a foster parent, it may also depend on whether the foster placement is permanent or temporary.

g. In the event of disagreement between legal parents or LARs on consent, first determine if there is equal legal authority, provided for in a divorce degree or court order. Among parents or LARs with equal legal authority, Healthcare Resolutions can assist with developing consensus and for clinical conflict management (Reference (j)).

h. When treating minors without parental consent outside the U.S. and its territories, the MTF director must work within the general principles of American law, host nation sovereignty/Status of Forces Agreements (SOFA) (when not in conflict with federal law and DoD policy) and in consultation with the servicing DHA Legal Office. MTF directors, in consultation with the servicing DHA Legal Office, may tailor policy on treatment of minors to be sensitive to host nation sensibilities, including setting minimum ages of consent. Unless modified by host nation law or a SOFA, a minor who is authorized care overseas is defined as a patient less than 18 years of age who maintains SOFA dependent status and is not otherwise emancipated by virtue of marriage or military service. Unless modified by host nation law or a SOFA, and consistent with the general principles of American law, a mature minor is further defined as being of sufficient age (age 15 or older) who, in the licensed independent practitioner's opinion, is also capable of making important decisions on their own behalf. Each country may interpret that provision differently — particularly when it comes to children; hence, caution should be exercised when treating children that may be of the age of consent in the host nation.

i. In states that recognize the "mature minor" doctrine and when treating minors without parental consent outside the U.S. and its territories (when not in conflict with host nation sovereignty/SOFAs and not in conflict with federal law and DoD policy), when medical needs for contraceptive services are requested by a minor, if the DHA healthcare provider/practitioner is satisfied the minor meets the requirements in the definition of a "mature minor," the consent of the minor is sufficient to provide treatment. In this situation, notice to, or consent from, the minor's parent, legal guardian, surrogate decision maker, or sponsor is not required. The

provider shall ensure documentation of their assessment of the minor as cognitively mature to give informed consent is clearly documented in the EHR. The DHA healthcare provider/practitioner will also encourage the minor to involve their parents, legal guardian, surrogate decision maker, or sponsor in these discussions and inform the minor of limitations on patient confidentiality. This discussion is important because a parent, legal guardian, surrogate decision maker, or sponsor may inadvertently learn about the care the mature minor consented to in different ways (e.g., a patient customer survey or a bill).

(1) Some complicating circumstances may necessitate the notification of a minor's parent, legal guardian, surrogate decision maker, or sponsor. These include life threatening conditions, conditions that may require the removal of reproductive organs, or if there is a change in behavior that brings into question the maturity with which they are approaching their healthcare that may result in potential danger to themselves or others. In these complicating circumstances, healthcare personnel should consult with the appropriate servicing DHA Legal Office for awareness and input into the specific situation.

(2) The provisions in References (n) and (o) apply to those individuals meeting the definition of a mature minor, to include the processes and procedures for DHA healthcare providers/practitioners who, with a matter of conscience or moral principle, cannot provide this care.

(3) This guidance also applies to staff at MTFs/DTFs located in a state or territory but providing treatment to patients who are physically located outside a state or territory, via virtual or telehealth.

(4) Records generated from the evaluation, care, and treatment of minors consistent with this guidance will be treated with the same degree of sensitivity as with adults receiving evaluation, care, and treatment for these conditions.

j. Local MTF/DTF guidance needs to address applicable laws and policies and the DHA servicing DHA Legal Office can assist with questions about particular situations regarding informed consent and confidentiality, particularly for minors on:

(1) Reproductive counseling and care for pregnancy and pregnancy-related conditions;

(2) Counseling for drug, alcohol, and tobacco abuse;

(3) Mental health treatment; including medications;

(4) Counseling and treatment for sexually transmitted diseases;

(5) Medical conditions where there is an imminent threat to life or limb;

(6) Contraceptive counseling and treatment;

(7) Counseling and treatment following rape and other sexual assaults;

(8) Permission to disclose of reports of tests or procedures to parents or LARs of a minor.

k. For minors who arrive at the MTF/DTF in need of treatment or a procedure, and there is no parent or LAR physically with them, the following steps should be taken:

(1) If it is an emergency situation, as described in Paragraph 8a, Emergency Medical Exceptions, treat the patient. The healthcare team works with Patient Administration, if needed, to locate the parent or LAR as soon as possible, without delaying emergency treatment. Obtaining informed consent itself remains the DHA healthcare provider's/practitioner's responsibility.

(2) If it is not an emergency, the healthcare team works with Patient Administration, if needed, to locate the parent or LAR. Consistent with applicable law, this individual can consent over the telephone, can come to the facility, or can provide written authorization for another to consent. Obtaining and documenting informed consent itself remains a responsibility of the DHA healthcare provider/practitioner.

l. Online access by parents or LARs to a minor's electronic medical record is detailed in Reference (q).

10. SPECIAL CONSIDERATION CONSENT FOR TREATMENT OF PATIENTS WITH A MENTAL HEALTH DISORDER

a. An adult who is capable of making healthcare decisions may consent for treatment of mental health disorder. Some jurisdictions recognize that an adult patient, while capable of making medical decisions, may appoint an agent to consent for treating a mental health disorder, including the diagnosis, evaluation, treatment, case management, or rehabilitation of any mental health disorder in the event the adult becomes incompetent or lacks decision-making capacity and has a need for mental health services.

b. For adults who are incapable of making medical decisions and in need of treatment for a mental health disorder, there are some state laws that impact who can consent for the treatment.

c. In some jurisdictions, minors, who attain a certain age, may consent to consultation, diagnosis, and treatment of mental health or emotional disorders; however, they may be unable to refuse consultation, diagnosis, or treatment for a mental health or emotional disorder for which a parent or LAR has given consent.

d. Consult with the servicing DHA Legal Office regarding applicable laws.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

AI	Administrative Instruction
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DoD	Department of Defense
DRM	Direct Reporting Markets
DTF	Dental Treatment Facility
EHR	Electronic Health Record
LAR	Legally Authorized Representative
MA	Medical Affairs
MTF	Military Medical Treatment Facility
OF	Optional Form
SOFA	Status of Forces Agreement

PART II. DEFINITIONS

Applicable law. Includes federal law and regulations, DoD policies, DHA policies, and state and/or local laws or policies when the state and/or local laws or policies are not contrary to federal law and DoD policy.

Contraceptive Services. Contraceptive services encompass medical counseling or treatment aimed at preventing pregnancy, including short and long-acting reproductive contraception medications and devices, any required examinations, and tests related to reproductive sexuality and prevention of sexually transmitted infections.

DHA Licensed Independent Healthcare Practitioners/Providers. Any member of the Armed Forces, civilian employee of the Department of Defense, or contractor under Title 10, United States Code, Section 1091 and as defined in Reference (g) who are authorized by the Department of Defense to perform health care services.

Dental Care. The American Dental Association defines Dentistry as the evaluation, diagnosis, prevention, and/or treatment (nonsurgical, surgical, or related procedures) of diseases, disorders and/or conditions of the oral cavity, maxillofacial area and/or the adjacent and associate structures and their impact on the human body; provided by a dentist within the scope of their

education, training, and experience, in accordance with the ethics of the profession and ethical law.

General Consent. General consent for treatment that could be applied generally to any patient seeking routine care, preventative care, evaluation, assessment diagnostic procedures.

Informed consent. As indicated in Reference (h), an agreement or permission accompanied by notice about the care, treatment, or service that is the subject of the consent. Informed consent is a process of communication that takes place between a patient and health care provider so that the patient is informed of the risks, benefits, and alternatives to the medical treatment being proposed so that the patient can make a knowledgeable decision on their health care. Informed consent recognizes and respects patient autonomy in medical decision-making. Informed consent is not limited to surgical procedures. The informed consent process is applied to treatments and procedures for specific clinical management of individual patients by their care provider.

Implied Consent. Consent arising by reasonable inference from the conduct of the patient, but with no specific words of consent communicated. Generally expressed informed consent is not required for simple or common medical procedures like a blood draw where the related risks are minimal and commonly understood. Implied consent applies only when a responsible licensed independent health care provider/practitioner can reasonably presume by patient's conduct that the patient knows the risks, benefits, and alternatives to the proposed treatment (including the right to refuse treatment).

Learners. Learners include, but are not limited to residents, medical students, advanced practice providers (such as nurse practitioners and physician assistants) students, and other applicable trainees.

Legal Incompetence. Legal incompetency of an individual means a declaration of such individual's incompetency, whether for insanity, age, disability, or other reason, by a court of competent jurisdiction.

Legally Authorized Representative. Any individual person (e.g., guardian, surrogate, healthcare agent), judicial body or other body of individuals who is legally authorized under state and federal law to give informed consent to medical treatment on behalf of a designated person.

Mature Minor. A minor of sufficient age who, in the licensed independent practitioner's opinion, is also capable of making important decisions on their own behalf. For MTFs overseas, unless modified by host nation law or a SOFA, and consistent with the general principles of American law, a mature minor is age 15 or older who, in the licensed independent practitioner's opinion, is capable of making important decisions on their own behalf.

Material Change in Circumstances. Something that a reasonable patient would consider relevant to their treatment decision and to their ability to make an intelligent choice.

Medical Care. The generally used term which pertains to the diagnosis and treatment of illness, injury, pregnancy, and mental disorders by trained and licensed or certified health professionals.

For purposes of TRICARE, the term "medical" should be understood to include "medical, psychological, surgical, and obstetrical," unless it is specifically stated that a more restrictive meaning is intended.

Person Providing Informal Kinship. Some states may recognize, as a LAR decision maker, an individual who is not a relative to the patient but someone with a relationship to that patient. Thus, this person may be able to consent for a patient as outlined in applicable state law.

Therapeutic Privilege. Is the right of a physician not to disclose information that would pose a serious physical or psychological threat to a patient. The therapeutic privilege is an exception to the general rule of informed consent. It is usually applied in situations where the disclosure of the information itself could pose serious and immediate harm to the patient. This should be based on sound medical judgment, but local legal requirements may prohibit the therapeutic privilege exception or not recognize it. However, the exception of therapeutic privilege does not apply when disclosure will merely lead to refusal of care that the physician thinks advantageous. It is also termed as therapeutic exception. When the responsible licensed independent healthcare practitioner/provider seeks to withhold material risk information from a patient, they should consider alternatives, such as a more gradual, but still timely, release of relevant information or, consider discussing the situation with another appropriately qualified provider and, if available, the patient's family members. Consultation with the MTF Ethics Committee may be appropriate. The responsible licensed independent healthcare practitioner/provider must clearly document in the medical record the rationale for asserting this exception, the nature and type of consultation, and family discussion or other actions taken, such as Ethics Committee consultation. Both the responsible licensed healthcare practitioner/provider and consulting practitioner/provider sign the entry.

Treatment or Procedure. Treatment is defined as the management and care of a patient for the purpose of combating disease, injury, or a disorder. A procedure is defined as a treatment, operation or intervention that is generally potentially painful, invasive or involves sedation or anesthesia for the purpose of diagnosing, combating disease, injury, or disorder in the care of a patient.

Oral Consent. A verbal consent is where a patient states their consent to a procedure verbally but does not sign any written form.

Written Consent. The process of written consent occurs when a form that is a representation of the conversation that captures the treatment plan for the patient is signed by that patient or LAR.