INFORMED CONSENT FOR CLINICAL TREATMENTS AND PROCEDURES

1. REASONS FOR ISSUE. This Veterans Health Administration (VHA) Handbook clarifies and updates VHA national policy on informed consent. It discusses the goals, scope, and key concepts related to patients' informed consent for clinical treatments and procedures and the related responsibilities of VHA staff (see VHA Handbook 1200.5(1) and Handbook 1058.03 for VHA policy on informed consent for research.). **The provisions of this VHA Handbook take effect August 17, 2009.**

2. SUMMARY OF MAJOR CHANGES.

a. Amendment dated June 25, 2020:

(1) Updates informed consent requirements to align with 38 Code of Federal Regulations (C.F.R.) § 17.32, Informed Consent and Advance Directives.

(2) Expands the approved communication modalities that may be used when in-person informed consent discussions with patients (or surrogates) are not possible.

(3) Expands the approved communication modalities that may be used to transmit a signed consent form when it is not possible to obtain the patient (or surrogate's) signature in-person.

(4) Allows patients (or surrogates) with physical impairments to place an "X", thumbprint, or stamp on a consent form in lieu of a signature or to designate a third party to sign a consent form on behalf of the patient (or surrogate)..

(5) Removes the special processes related to consent for "unusual or extremely hazardous treatments or procedures" as VHA no longer performs such treatments or procedures and the informed consent process itself provides the authorization for all treatments and procedures.

(6) Removes the requirements related to the withdrawal and withholding of life-sustaining treatment for patients who lack decision making capacity and have no surrogate as these requirements are included in VHA Handbook 1004.03, Life-Sustaining Treatment Decisions: Eliciting, Documenting, and Honoring Patients' Values, Goals, and Preferences.

(7) Allows the practitioner to delegate the responsibility of providing clinical information during the informed consent discussion to other trained personnel. The practitioner must personally verify with the patient (or surrogate) that the patient (or surrogate) has been appropriately informed and voluntarily consents to the treatment or procedure.

b. Amendment dated April 4, 2019:

(1) Removed the requirement to provide written educational materials to patients recommended for Human Immunodeficiency Virus (HIV) testing, as this requirement was removed with the publication of VHA Directive 1113, Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities, dated May 5, 2015.

(2) Removed the requirement for specific documentation of informed consent for tests for HIV and sexually transmitted diseases. An informed consent discussion is still required for tests for HIV and sexually transmitted diseases.

(3) Removed the requirement for signature informed consent for joint aspiration. Oral informed consent for joint aspiration is sufficient. Signature informed consent for joint injections is still required.

c. Amendment dated September 20, 2017 removed the requirement for specific documentation of informed consent for tests for Hepatitis B (HBV) and Hepatitis C (HCV). An informed consent discussion is still required for tests for HBV and HCV.

d. When it was published on August 14, 2009, VHA Handbook 1004.01:

(1) Incorporated new regulatory changes as follows:

(a) Extended the time period during which a signed consent document remains valid from 30 to 60 days;

(b) Eliminated the requirement for a third party witness (except in specific circumstances);

(c) Expanded the types of practitioners authorized to obtain informed consent;

(d) Eliminated the signature consent requirement for Human Immunodeficiency Virus (HIV) testing; and

(e) Eliminated the requirement for mandatory pre-test and post-test counseling for HIV.

(2) Mandated the use of iMedConsent™ software program to document the informed consent process (except in specific circumstances) and, if iMedConsent™ cannot be used, mandates the use of Department of Veterans Affairs (VA) Form 10-431a, “Consent for Clinical Treatment or Procedure,” or VA Form 10-0431b, “Consent for Transfusion of Blood Products,” General Services Administration (GSA) Optional Form (OF) 522, “Authorization for Administration of Anesthesia and Performance of Operations,” can no longer be used to document informed consent.

(3) Eliminated the signature consent requirement for medical care delivered by home telehealth, unless the medical care delivered meets the usual requirements for signature consent.

(4) Ascribed responsibilities to the National Center for Ethics in Health Care.

(5) Clarified informed consent procedures for collecting and releasing evidentiary materials and the requirement for signature informed consent for forensic examination.

(6) Clarified informed consent requirements and procedures for disclosure of protected information under Title 38, United States Code, Section (U.S.C.), Section 7332, (i.e., HIV test results, sickle cell disease, and alcohol and substance abuse).

(7) Clarified procedures for obtaining informed consent from patients when testing is needed to treat an employee who has experienced an occupational exposure to the bodily fluids of the patient.

3. RELATED ISSUES. VHA Handbook 1004.02, Advance Care Planning and Management of Advance Directives, dated December 24, 2013; VHA Handbook 1004.03, Life-Sustaining Treatment Decisions: Eliciting, Documenting, and Honoring Patients' Values, Goals, and Preferences, dated January 17, 2017; VHA Handbook 1004.05, iMedConsent™, dated December 10, 2014; and VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain, dated May 13, 2020.

4. RESPONSIBLE OFFICE: National Center for Ethics in Health Care (10E1E) is responsible for the contents of this Handbook. Questions are to be addressed to the Center at vhaethics@va.gov or (202) 632-8457.

5. DOCUMENTS RESCINDED. VHA Handbook 1004.1, dated January 29, 2003, is rescinded.

6. RECERTIFICATION. This document is scheduled for recertification on or before the last working day of August 2014. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

/s/ Gerald M. Cross, MD, FAAFP
Acting Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Distribution List 8/14/09

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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INFORMED CONSENT FOR CLINICAL TREATMENTS AND PROCEDURES

1. PURPOSE

This Veterans Health Administration (VHA) Handbook clarifies and updates VHA's national policy on informed consent. It discusses the goals, scope, and key concepts related to patients' informed consent for clinical treatments and procedures and the related responsibilities of VHA staff (see VHA Handbook 1200.05(1) and VHA Handbook 1058.03 for VHA policy on informed consent for research.).

2. BACKGROUND

VHA is committed to providing a health care environment that supports respect for patients and protects their right to autonomous, informed participation in health care decisions. These essential elements of quality health care are formalized in this national policy that establishes a process for informing patients about health care options and obtaining their consent prior to treatment.

3. DEFINITIONS

a. **Best Interests.** Best Interests are the standards to be used by surrogate decision makers to guide health care decisions when the patient's specific values and wishes are unknown. The surrogate, together with the health care team, uses this standard to determine the optimal outcomes for the patient and the interventions most likely to produce them. In making that determination the surrogate must take into account the patient's cultural, ethnic, and religious perspectives, if known.

b. **Close Friend.** A "close friend" is considered any person 18 years or older who has shown care and concern for the patient's welfare and is familiar with the patient's activities, health and religious beliefs, and values. The close friend must present a signed, written statement (to be placed in the patient's electronic health record) describing (with specific examples) that person's relationship to, and familiarity with, the patient. Social Work Service, or other staff, must verify and document in the patient's electronic health record that this requirement has been met.

c. **Coercion.** Coercion is defined as influencing, or attempting to influence, the patient's (or surrogate's) choice of treatment by use of threat(s), inducement(s), or misleading information.

d. **Competency.** In relation to decision-making capacity, competency is a legal determination made by a court of law that a patient has the requisite capacities to make a medical decision. ***NOTE:*** *This is in contrast to the term "decision-making capacity," which is a clinical determination made by the practitioner.*

e. **Decision-Making Capacity.** Decision-making capacity is a clinical judgment about a patient's ability to make a particular type of health care decision at a particular time. In clinical practice (and law), a patient's decision-making capacity is generally presumed; however, when the patient's medical condition or observed behavior raises questions about the patient's decision-making capacity, the responsible practitioner must make an explicit determination based on an assessment of the patient's ability to do all of the following:

(1) Understand the relevant information;
(2) Appreciate the situation and its consequences;
(3) Reason about treatment options; and
(4) Communicate a choice.

NOTE: *In contrast, "competence" is a legal determination made by a court of law.*

f. **Health Care Agent.** A health care agent (HCA) is a person selected by the patient and named in a Durable Power of Attorney for Health Care (DPAHC) to make health care decisions on the patient's behalf if, or when, that individual cannot do so. In VHA, a HCA is first in the hierarchy of surrogate decision makers and is authorized to make decisions about all types of health care on the patient's behalf. (See VHA Handbook 1004.02 and Department of Veterans Affairs (VA) Form 10-0137, VA Advance Directive: Living Will and Durable Power of Attorney for Health Care (DPAHC)).

g. **Human Immunodeficiency Virus (HIV) testing.** For the purposes of this Handbook, HIV testing refers to tests that are designed to determine whether a patient is infected with HIV. ***NOTE:*** *Tests that are used to help manage patients who are already known to have HIV disease are not considered HIV tests.*

h. **Legal Guardian.** A legal guardian is a person appointed by a court of appropriate jurisdiction to make decisions, including medical decisions, for an individual who has been judicially declared to be incompetent. The appointment may be of limited duration. Under VHA policy, legal guardians have the same authority to make health care decisions as any surrogate authorized under VHA policy. ***NOTE****: Financial or other types of limited guardianship do not always include the authority to make health care decisions.*

i. **Next-of-Kin.** Next-of-kin refers to a relative (18 years of age or older) of the patient who may act as surrogate in the following order of priority, as specified in Title 38 Code of Federal Regulations (CFR) §17.32: spouse, child, parent, sibling, grandparent, grandchild.

j. **Practitioner.** A practitioner is defined as any physician, dentist, or health care professional granted specific clinical privileges to perform the treatment or procedure. For the purpose of this Handbook, the term practitioner also includes:

(1) Medical and dental residents, regardless of whether they have been granted specific clinical privileges; and

(2) Other health care professionals whose scope of practice agreement or other formal delineation of job responsibility specifically permits them to obtain informed consent, and who are appropriately trained and authorized to perform the procedure or to provide the treatment for which consent is being obtained.

k. **Risks.** In relation to this Handbook, risk is defined as the possible undesirable outcomes of a treatment or procedure, including known side effects, complications, serious social or psychological harms, or other adverse outcomes.

l. **Signature Consent.** Signature consent refers to the patient's (or surrogate's) and practitioner's signature on a VA-authorized consent form.

m. **Substituted Judgment.** Substituted judgment is the standard used by surrogate decision makers who have specific knowledge of the patient's values and wishes pertaining to health care choices. This standard requires that the surrogate decide based on what the patient would have wanted if the patient were capable of expressing those preferences. That decision may not necessarily coincide with what the surrogate and health care team otherwise would consider optimal for the patient.

n. **Surrogate Decision Maker ("Surrogate").** Surrogate refers to an individual authorized under VHA policy to make health care decisions on behalf of a patient who lacks decision-making capacity.

o. **VA-Authorized Consent Form.** For the purposes of documenting informed consent for clinical treatments and procedures that require signature consent, the VA-authorized consent form refers to the use of the iMedConsent™ software program to conduct the informed consent discussion, capture electronic signatures, and file the completed document electronically in the patient's record. Printed VA Form 10-0431a, Consent for Clinical Treatment or Procedure, VA Form 10-0431b, Consent for Transfusion of Blood Products, and VA Form 10-0431c, Consent for Long-Term Opioid Therapy for Pain, are authorized for use if:

(1) The patient or surrogate declines to use the electronic signature pad, or

(2) There is a temporary system failure that prohibits proper use of the iMedConsent™ software program, or

(3) It is not possible to obtain a signed consent form in person (e.g., the patient (or surrogate) will not present to a VA medical facility prior to receiving a treatment or procedure), or

(4) The use of the equipment that supports the iMedConsent™ software program would introduce infection control issues (e.g., inability to adequately disinfect the signature pad used for a patient who is in isolation precautions). ***NOTE**: Paper VA*

consent forms are available through iMedConsent™ and at: http://vaww.va.gov/vaforms. This is an internal VA Web site and is not available to the public.

4. SCOPE

a. In VHA, patients have the right to accept or refuse any medical treatment or procedure recommended to them. Except as otherwise provided in this Handbook, all treatments and procedures require the prior, voluntary informed consent of the patient, or if the patient lacks decision-making capacity, the patient's authorized surrogate.

b. For many treatments or procedures, oral consent is sufficient. However, for certain treatments or procedures (see subpar. 13c(2)(a)), the patient's signature consent is required.

c. VHA does not recognize "general" or "blanket" consent for medical treatment, but requires the patient's consent for each treatment, procedure, therapeutic course of treatment for a particular problem or condition (e.g., inpatient or outpatient treatment for diabetes), or series of treatments (e.g., cycles of chemotherapy). When the proposed treatment plan involves multiple or recurrent treatments and procedures, it is generally not necessary to repeat the informed consent discussion for each new treatment or procedure, provided that the original consent encompassed the treatments or procedures to be performed. However, two circumstances exist where the informed consent discussion must be repeated and, when required, a new signed consent form must be obtained, they are:

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

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

d. Specific consent for any aspect of the recommended treatment or procedure that involves research sponsored by VA, as well as any human subjects research conducted on VA premises, must meet requirements of 38 CFR Part 16 and must be obtained in accordance with VHA Handbook 1200.05(1), VHA Handbook 1058.03, or superseding regulation and policy.

5. RESPONSIBILITIES OF THE VHA NATIONAL CENTER FOR ETHICS IN HEALTH CARE

The National Center for Ethics in Health Care is responsible for:

a. Providing ethics consultation services to the field regarding informed consent for clinical treatments and procedures, and for the informed consent process as outlined in this Handbook.

b. Collaborating with VHA Office of Quality and Safety to develop appropriate quality standards, metrics, and monitoring for implementation of informed consent procedures, including development of performance measures. ***NOTE:*** *Collaborative efforts include joint presentations of proposed performance measures to the Performance Measurement Workgroup for approval and target setting.*

c. Providing field support for informed consent procedures to include: educational information, policy interpretation and clarification, dissemination of best practices, and services from local or VISN IntegratedEthics Programs.

6. RESPONSIBILITIES OF THE VHA OFFICE OF PATIENT CARE SERVICES

The Office of Patient Care Services is responsible for developing and maintaining national policy Directives on scope of practice requirements specifying the permission to obtain informed consent for treatments and procedures provided by each category of non-physician health care professionals under their purview.

7. RESPONSIBILITIES OF THE OFFICE OF NURSING SERVICES

The VHA Office of Nursing Services is responsible for developing and maintaining national policy Directives on scope of practice requirements specifying the permission to obtain informed consent for treatments and procedures provided by each category of nursing health care professional.

8. RESPONSIBILITIES OF THE VETERANS INTEGRATED SERVICE NETWORK (VISN) DIRECTOR

The Veterans Integrated Service Network (VISN) Director is responsible for evaluating facilities within the VISN to ensure that each facility complies with the procedures for patients who lack decision-making capacity and who have no surrogate. ***NOTE:*** *This responsibility may be delegated to the VISN IntegratedEthics Advisory Board.*

9. RESPONSIBILITIES OF THE FACILITY DIRECTOR

The Facility Director is responsible for:

a. Ensuring informed consent processes outlined in this Handbook are followed;

b. Implementing the informed consent processes requiring multidisciplinary committee review for patients who lack decision making capacity and have no surrogate and for forced administration of psychotropic medications against the patient or surrogate's preferences; and

c. Having a procedure in place for identifying a surrogate (see subpar. 14a(2)).

10. RESPONSIBILITIES OF THE FACILITY SERVICE CHIEF

The facility Service Chief is responsible for oversight and monitoring of the informed consent process for patients who lack decision-making capacity and have no surrogate as outlined in this Handbook.

11. RESPONSIBILITIES OF THE PRACTITIONER

a. The practitioner who obtains the informed consent for the treatment or procedure must follow the processes outlined in this Handbook.

b. The practitioner who will perform the treatment or procedure must ensure that the informed consent was obtained, even when the practitioner performing the treatment or procedure is not the same person as the practitioner who obtained the informed consent.

12. DETERMINATION OF DECISION-MAKING CAPACITY

a. In order to obtain informed consent, the practitioner must first determine whether the patient has decision-making capacity. Patients are presumed to have decision-making capacity unless: an appropriate clinical evaluation determines that the patient lacks decision-making capacity, the patient is a minor, or the patient has been ruled incompetent by a court of law (see subpars.12e and 12f). For patients who have decision-making capacity, the practitioner must undertake the informed consent process with the patient as described in paragraph 13. For patients who lack decision-making capacity, practitioners must comply with paragraph 13, as well as paragraph 14.

b. The practitioner must perform (or obtain) and document a clinical assessment of decision-making capacity for any patient suspected of lacking decision-making capacity.

c. If the practitioner determines that the patient is likely to regain decision-making capacity, the practitioner must wait until the patient's decision-making capacity returns, and then undertake the informed consent process with the patient, provided that delaying the recommended treatment or procedure would not adversely affect the patient's condition. If the practitioner determines that the patient is unlikely to regain decision-making capacity within a reasonable period of time, an authorized surrogate must be sought.

d. When the determination of lack of decision-making capacity is based on a diagnosis of mental illness, a psychiatrist or licensed psychologist must be consulted in order to ensure that the underlying cause of the lack of decision-making capacity is adequately addressed. However, even in this instance, the 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.

e. If the patient is considered a minor under State law in the jurisdiction where the VHA 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 legal guardian.

f. 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. If a 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 practitioner must discuss this with the legal guardian and seek advice from the local IntegratedEthics program or District Chief Counsel.

13. INFORMED CONSENT PROCESS

For patients who have decision-making capacity, the informed consent process involves the following outlined procedures. The same process applies to surrogates who make decisions for patients who lack decision-making capacity, except as noted in paragraph 14.

a. **Informing the Patient.** During the informed consent process, the practitioner must engage the patient (or surrogate) in a discussion about the treatment or procedure. Ideally, the informed consent discussion is conducted in person; however, face-to-face discussions are not always possible. The informed consent discussion may be conducted by telephone, video conference, or other VA-approved electronic modalities if it is not possible to conduct the informed consent discussion in person or if it could introduce infection control issues, or if the patient expresses a preference for one of these modalities. As part of the informed consent discussion, the practitioner must:

(1) Provide information that a reasonable person in the patient's situation would expect to receive in order to make an informed choice about whether or not to undergo the treatment or procedure.. ***NOTE:*** *The practitioner may delegate the responsibility of providing information to other trained personnel, but must personally verify with the patient (or surrogate) that the patient (or surrogate) has been appropriately informed and voluntarily consents to the treatment or procedure.*

(a) For treatments and procedures that are low risk and are within broadly-accepted standards of medical practice, it is sufficient to obtain oral consent for the entire treatment or procedure without explicitly discussing each of its component elements; for example, a practitioner may obtain consent for a panel of routine blood tests without explicitly discussing that the panel includes tests for sodium, potassium, and chloride.

(b) For tests that provide information that is extremely sensitive or that may have a high risk of significant consequences (e.g., physical, social, psychological, legal, or economic) that a patient might reasonably want to consider as part of the consent decision, the informed consent discussion must include information a reasonable

person in the patient's situation would expect to receive in order to make an informed choice about whether or not to undergo the test. These tests include, but are not limited to, specific tests to identify illicit drug use, alcohol intoxication, Methicillin-Resistant Staphylococcus Aureus (MRSA), and inheritable genetic abnormalities. For these tests, practitioners must obtain specific consent and follow the informed consent process as outlined in the remainder of this paragraph. Signature consent is not required; oral informed consent noting each specific test discussed is sufficient and must be documented in the patient's electronic health record (see subpar. 13c(1)). A brief statement such as "patient consented to MRSA test" is sufficient.

(2) Describe the recommended treatment or procedure in language that is understandable to the patient. ***NOTE:*** *An interpreter must be provided, if necessary, to achieve this purpose (see current VHA policy regarding Limited English Proficiency Title VI Prohibition Against National Origin Discrimination in Federally-Conducted and Federally-Assisted Programs and Activities*). ***NOTE:*** *Educational material regarding testing and treatment for HIV and other sexually transmitted infections are available at* https://www.hiv.va.gov/products/index.asp*.*

(3) Give a clear and concise explanation of the patient's condition(s) or diagnosis(es) that relates to the recommended treatment or procedure.

(4) Describe the name, nature, and details of the recommended treatment or procedure, and the indications for that course of action, including the likelihood of success of the recommended treatment or procedure for that particular patient.

(5) Describe the expected benefits and known risks associated with the recommended treatment or procedure, including problems that might occur during recuperation. For example, discuss the risks of teratogenicity to the fetus when prescribing medications to women of childbearing age. Risks of minor seriousness 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 death or permanent disability.

(6) Describe reasonable alternative treatments and procedures. The practitioner must:

(a) Explain why the recommended treatment is thought to be more beneficial to the patient than the alternatives.

(b) Describe any expected benefits and known risks associated with the alternative treatments and procedures must also be described.

(c) Discuss reasonable alternatives including:

1. The option of no treatment or procedure and the expected benefits and known risks of that option; and

2. Potential emergency responses to known complications of the 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 complications of an angioplasty).

(7) Identify by name and profession the practitioner who has primary responsibility for the relevant aspect of the patient's care. Also identify by name and profession any other individuals responsible for authorizing or performing the treatment or procedure under consideration.

(8) Advise the patient if another practitioner will need to be substituted for any of those named. If the need for a substitution is known prior to initiating a treatment or procedure that requires signature consent, the patient must be informed of the change and this discussion and the patient's assent must be documented in the patient's electronic health record.

(9) Advise the patient if the recommended treatment is novel or unorthodox (e.g., non-traditional medicine, alternative medicine for which evidence of efficacy is lacking, and innovative surgical procedures that are not widely used).

(10) Advise the patient, when relevant, of the patient's responsibilities when undertaking the treatment or procedure (e.g., taking medications at home, changing own bandages).

(11) Obtain specific consent for any aspect of the recommended treatment or procedure that involves research in accordance with VHA Handbook 1200.05, or superseding regulation and policy.

(12) Ensure that the patient indicates understanding of the information provided. For example, the practitioner may ask the patient to describe the recommended treatment or procedure in the patient's own words.

(13) Encourage the patient to ask questions.

(14) Document all actions, as appropriate.

b. **Promoting Voluntary Decision-Making**

(1) The practitioner must promote the patient's voluntary decision-making during the informed consent process. The practitioner must not unduly pressure or coerce the patient into consenting to a particular treatment or procedure, but must instead convey that the patient is free to choose among any recommended treatments and procedures, including no treatment, or to revoke a prior consent without prejudice to the patient's access to future health care or other benefits.

(2) The practitioner is prohibited from attempting to persuade a patient to consent to a particular treatment or procedure by denying, or threatening to deny, the patient access to another procedure or treatment. However, in cases where in the medical judgment of the practitioner a particular treatment or procedure cannot be safely provided or performed without another treatment or procedure also being provided or performed, access to the first treatment or procedure may be made contingent on the patient's consent to the second treatment or procedure. For example, treatment with isotretinoin (Accutane™) may be made contingent on the patient's consent to a pregnancy test.

(3) Patients must not, as part of the routine practice of obtaining informed consent, be asked to sign consent forms "on the gurney" or after they have been sedated in preparation for a procedure. Exceptions may occur when there is an urgent clinical need.

c. **Documenting the Informed Consent Process.** Prior to undertaking any treatment or procedure, the practitioner must obtain informed consent and document the informed consent process in the patient's electronic health record. For certain treatments or procedures, the practitioner must also obtain the patient's signature consent (see subpar. 3L).

(1) **Documentation of Treatments and Procedures That Require Only Oral Informed Consent**

(a) Treatments and procedures that are low risk and within broadly-accepted standards of medical practice (e.g., administration of most drugs, vaccines, or for the performance of minor procedures, such as routine X-rays) require oral informed consent, but do not require signature consent. Both oral informed consent and signature consent must be documented in the patient's electronic health record. In accordance with VHA policy on documentation of patient records, documentation must be sufficient to serve as a basis to plan patient care, support diagnoses, and warrant treatment (see VHA Handbook 1907.01). In most cases, a brief statement such as "patient consented to treatment plan" is sufficient for these purposes.

(b) For tests, as discussed in subparagraph, 13a(1), that provide information that is extremely sensitive or that may have a high risk of significant consequences (e.g., physical, social, psychological, legal, or economic) that a patient might reasonably want to consider as part of the consent decision, the informed consent discussion must include information a reasonable person in the patient's situation would expect to receive in order to make an informed choice about whether or not to undergo the test. These tests include, but are not limited to, specific tests to identify illicit drug use, alcohol intoxication, Methicillin-Resistant Staphylococcus Aureus (MRSA), and inheritable genetic abnormalities. For these tests, signature consent is not required; oral informed consent noting each specific test discussed is sufficient and must be documented in the patient's electronic health record (see subpar. 13c(1)). A brief statement such as "patient consented to MRSA test" is sufficient. ***NOTE:*** *If specific*

consent is not obtained or documented, and the patient subsequently objects to the test, the patient must be notified of the patient's right to request that information pertaining to the test be expunged from the patient's electronic health record, consistent with VHA Handbook 1907.01.

(2) **Documentation of Treatments and Procedures That Require Signature Consent.** Prior to undertaking certain treatments and procedures, the practitioner must document the informed consent process in detail (as specified in subpars. 13c(2)(a) and 13c(2)(b)) and obtain the patient's signature on a VA authorized consent form.

(a) The patient's signature consent must be obtained for treatments and procedures that:

1. Can be reasonably expected to produce significant pain or discomfort to the patient;

2. Can be reasonably expected to produce pain or discomfort to the patient that is substantial enough to require sedation, anesthesia, or narcotic analgesia;

3. Can be reasonably considered to have a significant risk of complication or morbidity;

4. Require injections of any substance into a joint space or body cavity (excluding the intravascular space); or

5. Are listed in Appendix A.

NOTE: *It is not necessary to obtain a separate signature consent for sedation, anesthesia, or blood product transfusion if the combined consent form for the procedure already contains consent for sedation, anesthesia, or blood product transfusion, as in iMedConsent™*

(b) iMedConsent™ must be used to document patient (or surrogate) consent for treatments or procedures that require signature consent (See VHA Handbook 1004.05), unless:

1. The patient (or surrogate) declines to sign using the electronic signature pad;

2. There is a temporary system failure that prohibits proper use of the program;

3. It is not possible to obtain a signed consent form in person (e.g., the patient (or surrogate) will not present to a VA medical facility prior to receiving a treatment or procedure); or

4. Use of the equipment that supports the iMedConsent™ software program would introduce infection control issues (e.g., inability to adequately disinfect the signature pad used for a patient who is in isolation precautions).

NOTE: *Signatures may be captured synchronously in iMedConsent™, when the patient (or surrogate) and practitioner are in the same place at the same time, or asynchronously, allowing signatures to be captured at different times and/or locations. See https://vaww.ethics.va.gov/policy.asp for more information on the iMedConsent™ asynchronous signature capability. This is an internal website that is not available to the public.*

(c) When iMedConsent™ is not used due to one of the exceptions noted in subparagraph 13c(2)(b), signature consent must be documented on the appropriate printed VA Form 10-0431a, VA Form 10-0431b, or VA Form 10-0431c. If it is not possible to obtain a signed consent form(s) in person (e.g., the patient (or surrogate) will not present to a VA facility prior to receiving a treatment or procedure) the consent form(s) must be sent via fax, secure electronic mail, or other VA-approved modalities, for signature by the patient (or surrogate) and practitioner.

(d) If it is not possible to obtain a signed consent form in iMedConsent™ or on the appropriate printed VA consent form(s), the informed consent discussion must be audiotaped, videotaped, or witnessed by a second VA employee. If the informed consent discussion is audiotaped or videotaped, the practitioner must**:**

1. Call the patient or surrogate and identify and verify the parties on the line. ***NOTE:*** *This responsibility may be delegated.*

2. Ask the patient or surrogate for permission to audio tape the conversation or inform the surrogate that a second VA employee must witness the conversation. ***NOTE:*** *This responsibility may be delegated.*

3. If the patient lacks decision-making capacity, determine that the individual giving consent has the authority and is willing and available to act as surrogate and make health care decisions on behalf of the patient who lacks decision-making capacity.

4. Proceed with the informed consent discussion. ***NOTE:*** *This responsibility may not be delegated.*

5. Document the process.

(e) Audio tapes. If the discussion is audio taped, a typed transcript of the entire discussion with the date and time of the call must be filed in the patient's electronic health record, or scanned into the patient's electronic health record.

1. The transcriptionist must sign the document to certify that the transcript is an accurate verbatim account of the audio taped conversation. The audio tape must be clearly labeled with the:

a. Patient's name;

b. Last four digits of the patient's Social Security Number;

c. Name of treatment, or procedure, for which consent was obtained;

d. Name of surrogate and relationship to patient, if patient lacks decision-making capacity;

e. Date and time of conversation;

f. Name of the VHA medical facility; and

g. Name of the practitioner who obtained the consent.

2. Audio tapes must be kept under locked storage by the health records custodian until replaced by a signed consent form or disposed of in accordance with VHA Records Control Schedule 10-1. Refer to VHA Directive 6300(4), Records Management and VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3; VA Information Security Program for guidance on record retention and security mandates. ***NOTE:*** *The transcript must remain filed in the patient's electronic health record.*

(f). If the discussion is not audio taped, the practitioner must document compliance with the informed consent process in the patient's electronic health record as described in paragraph 13 and in subparagraph 14b and a second practitioner, or other VA employee, must witnesses the conversation and sign a report of contact or progress note that details the conversation.

(g) Documentation of the informed consent process for treatments and procedures that require signature consent must include all of the following elements:

1. The practitioner’s assessment of whether the patient has decision-making capacity.

2. The name(s) of all the practitioner(s) immediately responsible for the performance of the procedure, and if applicable, the supervision of the treatment or procedure, such as the resident physician and the attending physician.

3. A brief description of the recommended treatment or procedure.

4. A statement that relevant aspects of the treatment or procedure, including indications, benefits, risks, and alternatives including no treatment, have been discussed with the patient in language that the patient can understand; and that the patient indicated comprehension of the discussion.

5. A statement that the patient had an opportunity to ask questions.

6. A statement that the practitioner refrained from using coercion.

7. The date and time the discussion took place and whether the patient consented to the treatment or procedure.

8. The written or valid electronic signature of the patient or the patient's authorized surrogate.

9. The written or valid electronic signature of the practitioner writing the note (including the practitioner's legibly written name).

(h) In circumstances where the patient (or surrogate) is unable to sign the consent form due to a physical impairment, the patient 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 surrogate). If a patient (or surrogate) designates a third party, the third party must sign the consent form in the presence of the patient (or surrogate). Two adult witnesses (not including the practitioner who is obtaining the informed consent) must witness when the patient or surrogate place an "X", thumbprint, or stamp on the consent form or witness when a third party signs the consent form on behalf of the patient (or surrogate), and both witnesses must sign the consent form. The signatures of these witnesses on the form attest only to the fact that the witnesses saw the patient, surrogate, or third party sign the consent form.

(i) A properly-executed VA authorized consent form is valid for a period of 60 calendar days from the date signed. If during this 60-day period there is a significant change in the patient's condition that would reasonably be expected to alter the diagnosis or therapeutic decision, the consent is automatically rescinded and the informed consent process must be repeated for subsequent treatment.

1. Rescission of consent must be documented in the patient's electronic health record.

2. The practitioner who obtained consent or the practitioner responsible for the treatment or procedure for which consent was obtained must certify or verify the patient's rescission.

(j) The signed VA-authorized consent form must be filed in the patient's electronic health record, or scanned into Veterans Health Information Systems and Technology Architecture (VistA) Imaging. ***NOTE:*** *iMedConsent™ automatically generates and administratively closes a progress note after the electronic informed consent form is completed and saved to VistA imaging.* The patient or surrogate must be offered a paper copy of the completed consent form.

d. **When the Patient Chooses an Alternative Treatment, Including No Treatment, or Revokes Consent.** The patient may choose among recommended or alternative treatments and procedures that are consistent with accepted professional

standards, including no treatment. Or the patient may revoke a prior consent, even if that decision may increase the risk of serious illness or death, without prejudice to the patient's access to future health care or other benefits (see subpar. 13b(1)).

(1) 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 must document the patient's reason(s), if known, and the expected outcome.

(2) Whenever a patient revokes a prior consent, the responsible practitioner must:

(a) Write an addendum to the progress note associated with the prior consent. The addendum must state that the patient revoked the informed consent, document the date of the revocation, as well as the signing date(s) of any form(s) invalidated by this decision. The note must describe the substance of the discussion with the patient, and the reasons for the revocation.

(b) Request that the responsible party (typically, the Chief, Health Information Management Service) re-title the progress note associated with the revoked informed consent such that the first word of the note title is "Rescinded" followed by the local note title terminology. For example, change the note title "Informed Consent – General Surgery" to "Rescinded Informed Consent – General Surgery."

(3) If the patient's choice of treatment or procedure poses a potential hazard to others (e.g., declining treatment for active tuberculosis disease), the practitioner must notify the Chief of Staff, or designee, and consult with the local IntegratedEthics program officer or District Chief Counsel.

14. PATIENTS WHO LACK DECISION-MAKING CAPACITY

If the patient is judged to lack decision-making capacity (see par. 12), the following procedures apply (in addition to the procedures in par. 13):

a. **Identifying a Health Care Agent or Authorized Surrogate**

(1) **When a Health Care Agent Is Authorized and Available.** When a patient lacks decision-making capacity, the practitioner must make a reasonable inquiry as to the availability and authority of an advance directive naming a Health Care Agent. A Health Care Agent has the highest priority as a surrogate.

(2) **When No Health Care Agent Is Authorized and Available.** The practitioner, with the assistance of other staff, must make a reasonable inquiry as to the availability of other possible surrogates according to the order of priority listed in subparagraph 14a(3). Each facility must have a procedure in place for identifying surrogates, including, if necessary, examining personal effects, health records, and other VA records such as benefits and pension records. If a surrogate is identified, an attempt to contact that person by telephone must be made within 24 hours of the determination

that the patient lacks decision-making capacity. If a particular surrogate is unavailable or unwilling to serve as surrogate, the next surrogate in the established priority order must be sought. A surrogate must be sought even if the recommended treatment or procedure does not require signature consent.

(3) **Priority of Surrogates.** The surrogate is authorized to give informed consent on behalf of the patient in the following order of priority:

(a) Health Care Agent.

(b) Legal guardian.

(c) Next-of-kin. The next-of-kin is a relative, 18 years of age or older, in the following order of priority: spouse; child; parent; sibling; grandparent; grandchild.

(d) Close friend.

(4) **Disagreement between Individuals at the Same Surrogate Priority Level.** Where there are multiple individuals at the same priority level in the surrogate hierarchy and they do not agree about the recommended treatment or procedure, the practitioner must make reasonable efforts to reach a consensus. If consensus cannot be reached, the practitioner must choose the individual who is best able to represent the patient's values, wishes, and interests pertaining to the health care decision and document the reasons for choosing that individual. In cases where the choice is unclear, controversial, or if a potential surrogate contests the practitioner's choice of surrogate, the practitioner must consult with the local IntegratedEthics program officer or District Chief Counsel.

(5) **Documentation of the Process in Identifying an Authorized Surrogate**. The practitioner must document, in the patient's electronic health record, the process and outcome of efforts to identify a surrogate.

b. **Patients Who Have a Surrogate.** If it is determined that the patient lacks decision-making capacity and has a surrogate, that surrogate generally assumes the same authority and responsibilities as the patient in the informed consent process.

(1) The requirements for obtaining informed consent are described in paragraph 13, except as noted in the following:

(a) Disclosures otherwise required by this policy to be made to the patient must be made to the patient's surrogate to the extent permitted by law (see VHA Directive 1605.1 Privacy and Release of Information or superseding regulation and policy).

(b) Even though the patient lacks decision-making capacity, the practitioner must explain to the patient the treatment or procedure to which the surrogate has consented, if feasible.

(c) The surrogate's decision must be based on substituted judgment or, if the patient's values and wishes are unknown, on the patient's best interests (see paragraph 3 for definitions). If the practitioner considers the surrogate to be clearly acting contrary to the patient's values and wishes or the patient's best interests, the practitioner must notify the Chief of Staff, or designee, and consult with the local IntegratedEthics program officer or Regional Counsel before implementing the surrogate's decision.

(2) The requirements for documenting the informed consent process are described in paragraph 13. However, documentation for patients who lack decision-making capacity and have a surrogate must include the surrogate's name, relationship to the patient, authority to act as surrogate (whether Health Care Agent, legal guardian, next-of-kin, or close friend), and how the consent was obtained (e.g., in person, by telephone, by mail, or by fax). If the surrogate is a close friend, the required signed, written statement of their relationship and familiarity with the patient must be included.

c. **Patients Who Have No Surrogate.** If none of the surrogates listed in subparagraph 14a(3) is available, the practitioner may either contact District Chief Counsel for assistance in obtaining a guardian for health care decisions, or the practitioner may implement the following procedures in this paragraph that set out an alternative process for decision-making on behalf of patients who have no surrogate.

(1) **Treatments and Procedures That Do Not Require Signature Consent.** Medically-appropriate treatments and procedures that do not require signature consent may be performed in accordance with the following procedures, provided the procedures are low-risk and are within broadly-accepted standards of medical practice.

(a) The decision to provide a treatment or procedure must be based on substituted judgment or, if the patient's specific values and wishes are unknown, on the patient's best interests. If there is doubt regarding whether a treatment or procedure is consistent with the patient's values, wishes, or best interests, the practitioner must consult with the local IntegratedEthics program or Regional Counsel.

(b) Even if the patient lacks decision-making capacity, the practitioner must, where reasonable, attempt to explain the nature and purpose of the proposed treatment or procedure to the patient. The practitioner must indicate, in the patient's electronic health record, whether it was possible to communicate with the patient and if the patient appeared to understand the explanation.

(c) The practitioner must sign and date a progress note in the patient's electronic health record that describes the treatment or procedure and its indications.

(d) Treatment must not be provided indefinitely without review of the treatment plan at least every 6 months by the attending practitioner of record and the Service Chief, or designee, to ensure that clinical objectives are being met and the treatment plan is in the best interests of the patient. The attending of record and Service Chief must

indicate their approval of the treatment plan in writing in the patient's electronic health record.

(2) **Treatments and Procedures That Require Signature Consent.** In addition to all of the procedures listed in subparagraph 14c(1), for medically appropriate treatments and procedures that require signature consent but do not involve the withholding or withdrawal of life-sustaining treatment, the attending physician and Service Chief, or designee, must indicate their approval of the treatment decision in an addendum to the practitioner's progress note documenting the treatment or procedure and its indication(s) in the patient's electronic health record (see subpar. 13c(2)). ***NOTE:*** *Procedures for withholding or withdrawal of life-sustaining treatment for patients who have no surrogate are described in VHA Handbook 1004.03.*

15. CONSENT IN SPECIAL SITUATIONS

a. **Medical Emergencies**

(1) In medical emergencies the patient's consent is implied by law. The practitioner may provide necessary medical care in emergency situations without the patient's or surrogate's express consent when all of the following conditions are met:

(a) Immediate medical care is necessary to preserve life or avert serious impairment of the health of the patient; and

(b) The patient is unable to consent; and

(c) The patient has no surrogate, or the practitioner determines that waiting to obtain consent from the patient's surrogate would increase the hazard to the life or health of the.

(2) In a medical emergency, reasonable attempts to contact the patient's surrogate must be made as promptly as possible, before or after treatment is begun, to explain the nature of the treatment or procedure, the indications, and the expected outcome. The patient's previously stated wishes (e.g., Life-Sustaining Treatment plan and orders, verbal, advance directive) must be followed to the extent that they are known and are applicable to the current situation.

(3) When the patient's consent is not obtained due to the emergency exception:

(a) The practitioner must date and sign a progress note in the patient's electronic health record documenting the:

1. Patient's inability to provide consent;

2. Imminent danger to the health of the patient,;

3. Decision to undertake a particular treatment or procedure, and its rationale; and

4. Attempts that were made to identify and contact a surrogate.

(b) Whenever, due to the emergency exception, a treatment or procedure that requires signature consent has been provided without obtaining the patient's or surrogate's signature consent, the Service Chief must be notified and must review the record to verify that the emergency exception to obtaining signature consent has been appropriately applied. The Service Chief must document their review by either co-signing or writing an addendum to the progress note.

b. **Forced Administration of Psychotropic Medication.** The following represents the minimum in procedural constitutional due process protections afforded to patients by Federal courts. Because some states mandate more extensive procedural due process, VA personnel need to contact District Chief Counsel to determine if further protections are mandatory in their state. In addition, VA must follow state law regarding the forced administration of psychotropic medications in the context of involuntary commitments. In the case of involuntarily committed patients where the forced administration of psychotropic medication is against the will of a patient (or the surrogate does not consent), the following procedural protections must be provided:

(1) The patient (or surrogate) must be allowed to consult with independent specialists, legal counsel, or other interested parties = concerning treatment with psychotropic medication.

(2) Any recommendation to administer or continue psychotropic medication against the patient's wishes (or surrogate's wishes), must be reviewed by a multi-disciplinary committee appointed by the Facility Director for this purpose. That committee must include a psychiatrist or a physician experienced in prescribing psychotropic medications and managing serious mental illness. The committee functions as the patient's advocate and may not include members of the primary treatment team. The committee must submit its findings and recommendations in a written report to the Facility Director. The Facility Director must review the committee's recommendations and may concur, non-concur, or consult District Chief Counsel. The Facility Director's decision must be documented in the patient's electronic health record. Administration of psychotropic medications contrary to the patient's (or surrogate's) wishes may only be undertaken with the concurrence of the Facility Director.

(3) Continued therapy with psychotropic medication must be formally reviewed by the prescribing practitioner every 30 days and the results of the review documented in the patient's electronic health record.

(4) The patient, surrogate, or a representative on the patient's behalf may appeal the psychotropic medication treatment decision to a court of appropriate jurisdiction. The patient and surrogate, if applicable, must be informed of the right to appeal the decision.

(5) The practitioner must document compliance with these procedures in the patient's electronic health record.

c. **Consent for Collection and Release of Evidentiary Information and Material(s)**

(1) When a patient who is suspected of criminal wrongdoing or who is the victim of a suspected crime presents for medical care at a VHA facility, the patient may undergo two types of treatments or procedures. The different purposes, risks and benefits associated with each of the two processes require that informed consent be obtained and documented separately for the medical evaluation and the forensic examination. The processes are:

(a) Treatments or procedures that are designed to address the patient's specific medical and mental health needs, and

(b) A forensic examination to obtain all possible historical and physical evidence related to the suspected or alleged criminal wrongdoing.

(2) Informed consent for medical treatments and procedures must be obtained according to the informed consent process delineated in paragraph 13 of this Handbook.

(a) A separate signature informed consent is required to perform a forensic exam on a patient. Forensic examination includes collection of information and materials for the purpose of gathering legal evidence (e.g., rape kit). Evidentiary information or materials may be procured through history taking, physical examination, laboratory or diagnostic studies, medical assessment and care plan documentation, prescriptions, and follow-up to care related to the initial forensic evaluation.

(b) Informed consent to an examination for evidentiary collection needs to be obtained by a practitioner trained in conducting forensic evidentiary examinations. ***NOTE:*** *State law may limit the confidentiality of a suspected criminal's or alleged victim's health record. Patients suspected of criminal wrongdoing or alleged victims must, as part of the informed consent discussion, be made aware of the applicable limits to confidentiality in their state. Consult with District Chief Counsel as appropriate.*

(3) Because forensic examination is not necessary to preserve a patient's life or avert serious impairment to the patient's health, the practitioner must always obtain signature informed consent for the forensic examination. The emergency exception does not apply to forensic examination.

(4) If the patient is unable to provide signature informed consent because the patient lacks decision making capacity, procedures to identify an authorized surrogate

and appropriate procedures for obtaining signature informed consent for patients without decision-making capacity must be followed (see par. 14).

(5) If there is concern that the surrogate is acting contrary to the patient's stated wishes or best interests for any reason, or if there is suspicion that the surrogate is a party to abuse or neglect of the patient, refer to procedures for reporting and consultation in subparagraph 14b(1)(c).

(6) The patient has the right to accept or refuse any aspect of the medical treatment or forensic evidentiary examination, which may include:

(a) Examination for the presence of injuries.

(b) Evidence of assault, evidence of sexual assault, and collection of physical evidence.

(c) Photographs of injuries. VA Form 10-3203, Consent for Use of Picture and/or Voice, must be used if the pictures are not being used for treatment purposes.

(d) Further examination and collection as provided for by state law.

(7) Refusal of the forensic examination for evidence is not grounds for denial of medical treatment for injuries or appropriate testing for medical care. Refusal of any recommended treatment or procedure must be documented in the patient's electronic health record and those treatments or procedures must not be provided. ***NOTE:*** *Patients may opt to have forensic evidence collected anonymously and decide at a later date whether or not to cooperate with law enforcement. Consult with District Chief Counsel regarding state laws.*

(8) Specific conditions must be met before evidentiary information or materials may be disclosed without the patient's (or surrogate's) consent for use in legal proceedings (see VHA Directive 1605.1). ***NOTE:*** *Requirements may differ depending on whether the information was obtained for treatment purposes, or as part of a forensic examination. Consult with District Chief Counsel regarding state laws.*

(9) Evidentiary material must be collected, retained, and safeguarded according to VA Handbook 0730.

d. **Consent for Disclosure of Title 38 United States Code (U.S.C.) Section 7332-Protected Information**

(1) VA-generated records that reveal the identity, diagnosis, prognosis, or treatment of VA patients related to drug abuse, alcoholism or alcohol abuse, infection with HIV infection, or sickle cell anemia must be kept confidential (including the fact that an HIV test was conducted or the positive or negative results of HIV testing).

(2) This information may only be disclosed when specifically authorized, in writing, by the patient, patient's legal guardian, or patient's personal representative (including a health care agent designated in a Durable Power of Attorney for Health Care of a patient who lacks decision-making capacity), or disclosed under additional circumstances outlined in VHA Directive 1605.01, Privacy and Release of Information, including to the patient's surrogate when the patient lacks decision-making capacity and the practitioner deems the information necessary for the surrogate to make an informed decision regarding the patient's treatment. Unauthorized release of any confidential information, such as HIV test results, may result in criminal penalties or substantial fines. ***NOTE:*** *For questions refer to VHA Directive 1605.01 and consult the local Privacy Officer or District Chief Counsel.*

e. **Consent for Testing of a Source Patient after an Occupational Exposure**

(1) When an employee is inadvertently exposed to a patient's bodily fluids, tissues, or excretions (e.g., blood, urine, sweat, saliva, pus, fecal matter) there may be transmission of infectious pathogens (e.g., HIV, Hepatitis C, Hepatitis B, MRSA), contaminants (e.g., radiated isotopes), toxins, or other agents. When such an occupational exposure occurs, optimal treatment for the employee may depend upon the source patient's medical condition(s). Testing to determine the source patient's medical condition(s) may only be performed with the source patient's (or surrogate's) explicit informed consent and that consent must be documented according to procedures as outlined in subparagraph 13c. Source patients have the right to refuse testing or procedures requested for the purposes of diagnosis or treatment of employees who have experienced an occupational exposure.

(2) Informed consent for source patient testing may only be obtained after the occupational exposure has occurred. Consent may not be obtained prospectively, i.e., in case of a hypothetical or potential occupational exposure. For example, prior to a surgical procedure, patients may not be asked to provide consent to undergo Hepatitis C testing that might be needed if a member of the surgical team experiences a needlestick injury during the upcoming surgical procedure.

(3) To prevent coercion or undue influence on the source patient, informed consent for testing of a source patient after an occupational exposure must be performed by an employee who does not have a personal relationship with the exposed employee (e.g., friend, family member, former spouse) and, whenever possible, by an employee who is not professionally related to the employee or the patient. The exposed employee may never seek consent from the source patient without incurring consequences.

f. **Consent for Treatments or Procedures Delivered Using Telehealth**

(1) For most treatments or procedures that are delivered using telehealth, oral informed consent is sufficient. Signature consent is required for treatments or procedures delivered via telehealth if and only if the treatment or procedure meets one or more of the criteria listed in subparagraph 13c(2)(a), or is listed in Appendix A.

(2) Regardless of whether informed consent for the telehealth treatment or procedure requires signature consent, the practitioner must ensure that the patient is informed about:

(a) The likely differences between receiving care delivered using telehealth technologies and face-to-face care, and

(b) That patients are free to choose among available comparable treatments or procedures that use telehealth and those that do not.

NOTE: *Signature consent for research on the use of telehealth modalities or technologies is required according to existing VHA policies as noted in paragraph 4d.*

16. REFERENCES

a. Title 38 U.S.C. § 7331, 7332, and 7333.

b. Title 38 CFR §16 and 17.32.

c. Title 29 CFR 1910.1030.

d. VA Handbook 0730.

e. VHA Handbook 1004.02.

f. VHA Handbook 1004.03(1).

g. VHA Handbook 1004.05.

h. VHA Handbook 1058.03

i. VHA Handbook 1200.05(1)

j. VHA Handbook 1907.01.

k. VHA Directive 1605.1.

l. VA Form 10-0431a, Consent for Clinical Treatment/Procedure: https://vaww.va.gov/vaforms/medical/pdf/10-0431a-fill.pdf. ***NOTE:*** *This is an internal website and is not available to the public.*

m. VA Form 10-0431b, Consent for Transfusion of Blood Products: https://vaww.va.gov/vaforms/medical/pdf/10-0431b-fill.pdf. ***NOTE:*** *This is an internal website and is not available to the public.*

n. VA Form 10-0431c, Consent for Long-Term Opioid Therapy for Pain: https://vaww.va.gov/vaforms/medical/pdf/vha-10-0431C-fill.pdf. ***NOTE:*** *This is an internal website and is not available to the public.*

n. The Joint Commission, Comprehensive Accreditation Manual for Home Care, Patient-Focused Functions Section R1, Ethics, Rights and Responsibilities, Standards RI.1, RI.2. 2008.

o. The Joint Commission, September 2007 Comprehensive Accreditation Manual for Long Term Care, Section 1, Resident-Focused Functions: The Official Handbook, Section R1 Ethics, Rights and Responsibilities, Standards. RI.1, and RI.2, 2007. 2008.

p. Beauchamp TL and Childress JF, Principles of Biomedical Ethics. 5th edition. New York, Oxford University Press, 2001.

TREATMENTS AND PROCEDURES REQUIRING SIGNATURE CONSENT

NOTE: *The following list is not all inclusive (see subpar. 13c(2) of this Handbook for a general description of treatments and procedures that require signature consent).*

1. Surgical or invasive procedures, including but not limited to:

a. Any procedure done within an operating room;

b. Acupuncture (excluding auricular acupuncture);

c. Aspiration of body fluids or injection of therapeutic or diagnostic agents through the skin or into a body cavity (e.g., bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis). ***NOTE:*** *Signature informed consent is not required for joint aspiration. Oral informed consent is sufficient for joint aspiration. Signature informed consent for joint injections is required;*

d. Biopsy (e.g., breast, liver, muscle, kidney, genitourinary, prostate, bladder, skin);

e. Cardiac procedures (e.g., cardiac catheterization, cardiac pacemaker electrode insertion, electrical cardioversion, stress tests to include exercise and pharmacologic methods);

f. Central vascular access device insertion (e.g., arterial line, Swan-Ganz catheter, central venous line, peripherally inserted central catheter (PICC) line, Hickman catheter);

g. Electrocautery;

h. Endoscopy (e.g., bronchoscopy, colonoscopy, cystoscopy, laparoscopy);

i. Interventional radiology procedures (e.g., arthroplasty, angiography);

j. Photocoagulation;

k. Oral surgical procedures (including gingival biopsy);

l. Sterilization of reproductive capacity;

m. Thoracostomy;

n. Tracheostomy; and

o. Transjugular intrahepatic portal stent (TIPS).

2. Sedation, other than anxiolysis (level one sedation).

3. Anesthesia, other than low risk local anesthesia (e.g., topical numbing agents).

4. Blood product transfusion.

NOTE: *It is not necessary to obtain a separate signature consent for sedation, anesthesia, or blood product transfusion if the combined consent form for the procedure already contains consent for sedation, anesthesia, or blood product transfusion, as in iMedConsent™.*

5. Delivery of a child.

6. Laser Therapy.

7. Botox treatment for dystonia.

8. Dialysis (hemodialysis or peritoneal).

9. Electroconvulsive therapy.

10. Hazardous drugs (e.g., cancer chemotherapy, methadone for narcotic dependence, buprenorphine, thalidomide, clozapine, Retin A).

11. Photochemotherapy in combination with psoralens or other topical agents.

12. Lithotripsy.

13. High-risk imaging procedures where there is no other appropriate alternative diagnostic approach, such as:

a. Intravascular injection of iodinated radiographic contrast agents in high-risk patients (e.g., those with prior allergic reactions, renal failure or other risk factors);

b. Intravascular injection of gadolinium contrast agents in high-risk patients (e.g., those with prior allergic reaction to gadolinium or at risk of nephrogenic systemic fibrosis);

c. Radionuclide therapy (e.g., radioiodine for hyperthyroidism and thyroid cancer, radiostrontium or adiosamarium for palliation of painful metastases to bone, Zevulin or Bexxar therapy for lymphoma or other radionuclide therapies); and

d. Pregnant patient receiving intravascular contrast agents or x-radiation to the fetus.

14. Forensic Examination.