VHA 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.

2. SUMMARY OF MAJOR CHANGES: This handbook has undergone major changes in format and structure in order to clarify and facilitate the informed consent process. Specific emphasis has been given to:

a. The process of informed consent, including the issues of determining decision-making capacity, informing the patient, promoting voluntary decision making, and documenting the process;

b. The informed consent process for patients who lack decision-making capacity; specifically, patients who have surrogates and those who do not;

c. Consent in special situations such as medical emergencies, unusual or extremely hazardous treatments and procedures, forced administration of psychotropic medication, release of evidentiary information or materials, testing for Human Immunodeficiency Virus (HIV), and telemedicine and/or telehealth.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: National Center for Ethics in Health Care (10AE). Questions are to be addressed to the Center at (202) 273-6926.

5. DOCUMENTS RESCINDED: VHA Handbook 1004.1, dated November 7, 2001, is rescinded.

6. RECERTIFICATION: This document is scheduled for recertification on or before the last working date of January 2008.

Robert H. Roswell, M.D.
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 1/29/2003
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 1/29/2003

CONTENT

VHA INFORMED CONSENT FOR CLINICAL TREATMENTS AND PROCEDURES

PARAGRAPH **PAGE**

CONTENTS Continued

PARAGRAPH **PAGE**

VHA 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.

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.** The standard 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 use this standard to determine the optimal outcomes for patients and the interventions most likely to produce them. In making that determination the surrogate must also take into account the patient's cultural, ethnic, and religious perspectives, if known.

b. **Close Friend.** 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 filed in the medical record) describing (with specific examples) that person's relationship to and familiarity with the patient. Social Work Service, or other staff, must verify, in a signed and dated progress note, that this requirement has been met.

c. **Coercion.** 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 (see subpar. 3e), competency is a legal determination, made by a court of law, that a patient has the requisite capacities to make a medical decision. 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 for health care decisions has four major components: understanding, appreciating, formulating, and communicating. The first two components represent the patient's ability to understand and appreciate the nature and expected consequences of each health care decision. This includes understanding the known benefits and risks of the recommended treatment options, as well as any reasonable alternative options

including no treatment. The latter two components represent the ability to formulate a judgment and communicate a clear decision concerning health care. As used in this Handbook, "capacity" is a clinical determination made by the practitioner, in contrast to the term "competency," which is a legal determination made by a court of law.

f. **Health Care Agent.** The individual named in a Durable Power of Attorney for Health Care (DPAHC) document executed by the patient prior to losing decision-making capacity. This individual acts on the patient's behalf to make health care decisions, including the use of life-sustaining treatment when the patient is unable to make such decisions (see VHA Handbook 1004.2,and Department of veterans Affairs (VA) Form 10-0137, VA Advance Directive: Living Will and Durable Power of Attorney for Health Care (DPAHC)).

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

h. **Next-of-Kin.** 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.

i. **Practitioner.** Any physician, dentist, or health care professional who has been granted specific clinical privileges to perform the treatment or procedure. For the purpose of this Handbook, the term practitioner includes medical and dental residents, regardless of whether they have been granted clinical privileges.

j. **Risks.** The possible undesirable outcomes of a treatment or procedure including side effects, complications, serious social or psychological harms, or other adverse outcomes.

k. **Signature Consent.** The patient's (or surrogate's) signature on a VA authorized consent form.

l. **Substituted Judgment.** The standard to be 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 he or she 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.

m. **Surrogate Decision Maker ("surrogate").** An individual, committee, or decision-making process authorized under VHA policy to make health care decisions on behalf of a patient who lacks decision-making capacity.

n. **Telemedicine and/ or Telehealth.** Electronic communications and information technology used to provide and support health care when distance separates the participants. Telemedicine and/ or telehealth includes the remote monitoring of physiological data and video

visits. Telemedicine and/ or telehealth does not include the use of the telephone for direct audio consultation between practitioners and patients or surrogates.

o. **VA Authorized Consent Form.** A published, numbered, official VA Form such as OF 522, Request for Administration of Anesthesia and for Performance of Operations and Other Procedures, or a comparable form approved by the local VHA facility, including approved electronic consent forms.

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. The scope of informed consent may be limited to a one-time, single treatment or procedure, or may encompass consent for routine care of a particular problem or condition (such as asthma), or for a series of treatments (such as dialysis). When the proposed treatment plan involves multiple or recurrent treatments and procedures, it is generally not necessary to repeat the informed consent discussion. There are, however, two circumstances where the informed consent discussion must be repeated and a new consent must be obtained:

(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 should reasonably be expected to alter the original informed consent.

NOTE: *This Handbook does not address requirements pertaining to consent to participate in research. For VHA policy on informed consent to participate in research see VHA Manual M-3, Part I, Chapter 9, or superseding regulation and policy.*

5. RESPONSIBILITIES

a. The practitioner who will perform the treatment or procedure must ensure that the informed consent process outlined in the handbook is followed.

b. The Veterans Integrated Service Network (VISN) Director is responsible for evaluating facilities within the network to ensure that each facility complies with the procedures for patients who lack decision-making capacity and who have no surrogate (see subpar. 8c).

6. 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, or the patient is a minor, or the patient has been ruled incompetent by a court of law

(see subpar. 6e, and subpar. 6f). For patients who have decision-making capacity, the practitioner must undertake the informed consent process with the patient as described Paragraph 7. For patients who lack decision-making capacity, practitioners must comply with Paragraph 7 as well as Paragraph 8.

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 perform 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 is legally 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 ethics program and/or Regional Counsel.

7. 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 8.

a. **Informing the Patient.** During the informed consent process, the practitioner must:

(1) Provide information that a patient in similar circumstances would reasonably want to know.

(2) Describe the recommended treatment or procedure in language that is understandable to the patient. An interpreter must be provided, if necessary, to achieve this purpose.

(3) Give a clear and concise explanation of the patient's condition(s) or diagnosis(es) that relate 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 expected benefits and known risks associated with the recommended treatment or procedure, including problems that might occur during recuperation. 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 explain why the recommended treatment is thought to be more beneficial to the patient than the alternatives. Expected benefits and known risks associated with the alternative treatments and procedures must also be described. Reasonable alternatives discussed must include: the option of no treatment or procedure, and the expected benefits, and known risks of that option. Reasonable alternatives discussed must also include 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 patient's care. The names and professions of any other individuals responsible for authorizing or performing the treatment or procedure under consideration must also be disclosed.

(8) Advise the patient if another practitioner will 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 medical record;

(9) Advise the patient if the recommended treatment is novel or unorthodox;

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

(11) Obtain specific consent for any aspect of the recommended treatment or procedure that involves research in accordance with M-3, Part I, Chapter 9, or superseding regulation and policy.

(12) Ensure that the patient indicates understanding of all 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.

b. **Promoting Voluntary Decision-Making.** The practitioner must promote the patient's voluntary decision-making during the informed consent process. The practitioner must 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.

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 medical record. For certain treatments or procedures, the practitioner must also obtain the patient's signature consent (see par. 3).

(1) **Treatments and Procedures that do not Require Signature Consent.** Treatments and procedures that are low risk and are within broadly accepted standards of medical practice (e.g., administration of most drugs or for the performance of minor procedures such as routine X-rays) do not require signature consent. However, the informed consent process must be documented in the medical 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 M-1, Pt. I, Ch. 5).

(2) **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 subpar. 7c(2)(a) and subpar. 7c(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. Involve the use of sedation;

2. Involve the use of anesthesia or narcotic analgesia;

3. Can be reasonably expected to produce significant discomfort to the patient;

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

5. Require injections of any substance into a joint space or body cavity, including any non-vascular space;

6. Involve testing for human immunodeficiency virus (HIV); or

7. Are listed in Appendix A.

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

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, and if applicable, the supervision of the treatment or procedure, such as the resident physician and the attending.

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 could 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 practitioner writing the note (including the practitioner's legibly written name).

(c) A properly executed VA authorized consent form is valid for a period of 30 calendar days from the date signed. If during this 30 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. Rescission of consent must be documented in the patient's medical record. The practitioner who obtained consent must certify or verify the patient's rescission.

(d) The patient's and practitioner's signature on a VA authorized consent form must be witnessed by a third party who attests to the fact that the witness saw the patient and the practitioner sign the form. When the patient's signature is indicated on the VA authorized consent form by an "X," two adult witnesses (not including the practitioner) are required.

(e) The signed VA authorized consent form must be filed in the patient's medical record. The patient must be offered a copy of the completed consent form.

d. **When the Patient Chooses an Alternative Treatment, Including No Treatment, or Revokes Consent.**

(1) The patient may choose among recommended or alternative treatments and procedures, 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.

(2) 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.

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

8. PATIENTS WHO LACK DECISION-MAKING CAPACITY

If the patient is judged to lack decision-making capacity (see par. 6), the following procedures apply (in addition to the procedures in par. 7):

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 (see subpar. 3f for definition). 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 8a(3). Each facility must have a procedure in place for identifying surrogates including, if necessary, examining personal effects, medical 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 (see subpar. 3f for definition);

(b) Legal guardian or special guardian (see subpar. 3g for definition);

(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 (see subpar. 3h definition); and

(d) Close friend (see subpar. 3b definition).

(4) **Disagreement Between Surrogates at same Priority Level.** Where there are multiple surrogates at the same priority level in the 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 surrogate who is

best able to speak for the patient, and document the reasons for choosing that individual. In cases where the choice is unclear, the practitioner must consult with the local ethics program and/or Regional Counsel.

(5) **Documentation of the Process in Identifying an Authorized Surrogate**. The practitioner must document 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 7, except as noted below.

(2) 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 M-1, Pt I, Ch. 9, or superseding regulation and policy).

(3) 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.

(4) 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 subpar. 3a 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 ethics program and/or Regional Counsel before implementing the surrogate's decision.

(5) The requirements for documenting the informed consent process are described in subparagraph 7c; however, documentation for patients who lack decision-making capacity, but have a surrogate must also include the surrogate's name, relationship to the patient, authority to act as surrogate (whether DPAHC, legal guardian, next-of-kin, or close friend), and how the consent was obtained (in person, by telephone, by mail, or by facsimile (fax).

c. **Patients Who Have No Surrogate.** If none of the surrogates listed in subparagraph 8b(5) is available, the practitioner may either contact Regional Counsel for assistance in obtaining a guardian for health care decisions, or the practitioner may follow the 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 (see

subpars. 3b and 3l for definitions). If there is doubt regarding whether a treatment or procedure is consistent with the patient's values and wishes or the patient's best interests, the practitioner must consult with the local ethics program and/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 medical 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 medical record that describes the treatment or procedure and its indications.

(d) Treatment must not be provided indefinitely without periodic review by the primary treatment team and by an advocate for the patient. The primary treatment team must review the treatment plan to ensure that clinical objectives are being met. Someone outside the primary treatment team who can serve as the patient's advocate must review the treatment plan at least every 6 months to ensure it is in the patient's best interests.

(2) **Treatments and Procedures that Require Signature Consent.** For medically appropriate treatments and procedures that require signature consent, but do not involve the withholding and/or withdrawal of life-sustaining treatment, the following procedures apply (see subpar. 7c(2) for an explanation of procedures requiring signature consent). ***NOTE:*** *Procedures for withholding or withdrawal of life-sustaining treatment for patients who have no surrogate are described in subparagraph 8c(3).*

(a) The attending practitioner must sign and date a progress note in the medical record that describes the treatment or procedure and its indications; and

(b) The Chief of Service, or designee, must provide a signed and dated concurrence, in the patient's medical record, with the decision to perform the treatment or procedure, and the treatment's or procedure's indications.

NOTE: *In addition to the preceding, the provisions in subparagraph 8c(a) through subparagraph 8c(d) also apply to treatments and procedures that require signature consent.*

(3) **Withholding and/or Withdrawal of Life-sustaining Treatment.** VA patients have the right to have unwanted life-sustaining treatment withheld and/or withdrawn even if this action results in death. In order to ensure a decision consistent with the patient's best interests, there is a special process that must be followed when considering the withholding and/or withdrawal of life-sustaining treatment for a patient who lacks decision-making capacity and has no surrogate. Implementation of decisions to withhold and/or withdraw life-sustaining treatments must follow the guidelines set out in VHA Handbook 1004.3, and VHA Handbook 1004.2. In addition, <u>all</u> the following procedures must be followed <u>and</u> documented in the medical record:

(a) The attending practitioner participates in the discussion of the withholding and/or withdrawal of life-sustaining treatment with the treatment team, and recommends life-sustaining

treatment be withheld and/or withdrawn in a signed and dated progress note in the medical record.

(b) A multi-disciplinary committee appointed by the facility Director must consider the procedural and ethical validity of the recommendation to withhold and/or withdraw life-sustaining treatment(s). ***NOTE:*** *An existing local ethics committee, a subcommittee of the local ethics program, or an independent group may serve this function.* The committee functions as the patient's advocate and may not include members of the primary treatment team. The committee must use the substituted judgment standard (where possible) or the best interests standard (see subpars. 3b and 3l for definitions). To the extent feasible, the committee must seek input from representatives of the patient's cultural, ethnic, or religious group. The committee must then submit a written report to the Chief of Staff that describes its findings and recommendation(s).

(c) The Chief of Staff, or designee, must approve or disapprove the committee's recommendation to withhold and/or withdraw life-sustaining treatment. The committee's recommendation(s) and the Chief of Staff's decision must be documented in the medical record.

(d) The facility Director must review the decision and may either concur, not concur, or request review by Regional Counsel. The final decision must be documented in the medical record. The withholding and/or withdrawal of life-sustaining treatment may only be undertaken with the concurrence of the facility Director.

d. **Surrogate Consent by Mail, Fax, Telephone, or E-mail.** Ideally, the informed consent discussion and signature consent (where required) will be conducted in person; however, face-to-face discussions are not always possible. This subparagraph outlines the procedures to follow when it is impractical to obtain a surrogate's consent in person.

(1) **Consent by Mail or Fax.** When informed consent is sought by mail or fax, the practitioner must enclose a letter addressed to the surrogate with a VA authorized consent form. The letter must provide the same information that generally would be supplied to the surrogate in a face-to-face discussion and must be signed by the practitioner. A copy of the letter must be filed in the patient's medical record. A fax copy of a completed consent form signed by the surrogate is adequate to proceed with treatment. Reasonable efforts must be made to ensure that the original form that the surrogate signed is returned and filed in the patient's medical record.

(2) **Consent by Telephone.** When consent is sought by telephone, the conversation must either be audio-taped or witnessed by a second VA employee.

(a) The practitioner must**:**

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

2. Ask the 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. Determine that the individual 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.

(b) Audiotapes. 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 medical record.

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

a. Patient's name;

b. Social Security Number;

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

d. Name of surrogate and relationship to patient;

e. Date and time of conversation;

f. Name of the VHA medical facility; and

g. Name of the practitioner who obtained the consent.

2. Audiotapes must be kept under locked storage by the medical records custodian until replaced by a signed consent form or disposed of in accordance with VHA Records Control Schedule 10-1. ***NOTE:*** *The transcript must remain filed in the patient's medical record.*

(c) If the discussion is not audio-taped, the practitioner must document compliance with the informed consent process in the medical record as described in Paragraph 7 and in subparagraph 8b. If a second practitioner, or other VA employee, witnesses the conversation, both the practitioner and the second employee must sign a report of contact, or progress note, that details the conversation.

(3) **Consent by E-mail.** Signature consent by E-mail is not permitted.

9. 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 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 or others; 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 patient or others.

(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 must be followed to the extent that they are known. If these wishes are contained in a written advance directive, the practitioner must ensure that the advance directive is valid and applies 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 medical record documenting the:

1. Patient's inability to provide consent;

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

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 treatment is provided in a medical emergency without the patient's or surrogate's express consent, the Chief of Staff or equivalent must sign and date the VA authorized consent form. This signature may be obtained after the clinical intervention, when necessary. If the Chief of Staff or equivalent is the treating practitioner, a second practitioner must sign the consent form.

b. **Unusual or Extremely Hazardous Treatments and Procedures.** No patient will undergo any treatment or procedure considered to be unusual or extremely hazardous, such as psychosurgery, except under extraordinary circumstances, subject to the following:

(1) Before treatment is initiated, the patient (or surrogate) must be given adequate opportunity to consult with independent specialists, legal counsel, or other interested parties of the patient's (or surrogate's) choosing. The patient's (or surrogate's) signature on a VA authorized consent form must be witnessed by someone who is not affiliated with the VA health care facility (e.g., spouse).

(2) If a surrogate makes the health care decision, a multi-disciplinary committee, appointed by the facility Director, must review the surrogate's decision before treatment is initiated to ensure that the decision to treat is consistent with the patient's wishes (or best interests, if the patient's wishes are not known). 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 Director may authorize treatment consistent with the surrogate's decision, or authorize the practitioner to seek a legal guardian or special guardian to make the health care decision.

(3) If there is no available surrogate, the practitioner must follow procedures similar to those outlined in subparagraph 8c(3) for the withholding and/or withdrawal of life-sustaining treatment, or request that a guardian be appointed to make health care decisions for the patient. ***NOTE:*** *Contact Regional Counsel for assistance.*

NOTE: *The practitioner must document compliance with all these procedures in the patient's medical record.*

c. **Forced Administration of Psychotropic Medication.** ***NOTE:*** *Administration of psychotropic medication to an involuntarily committed patient against the patient's (or surrogate's) wishes must meet Constitutional due process requirements.*

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

(2) Any recommendation to administer or continue psychotropic medication against the patient's (or surrogate's) will 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 who has psychopharmacotherapy privileges. The committee functions as the patient's advocate and may not include members of the primary treatment team. The facility Director must concur with the committee's recommendation to administer psychotropic medications contrary to the patient's (or surrogate's) wishes.

(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 medical 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 medical record.

d. **Release of Evidentiary Information and/or Material(s).** Information and/or other evidentiary material(s) that could be used for legal prosecutions include those collected during the diagnosis and treatment of a patient who is suspected of criminal wrongdoing or who is the victim of a suspected crime. The practitioner must ensure that proper informed consent for treatments and procedures is obtained from the patient (or surrogate, if applicable) and appropriately documented in the medical record. If there is concern that the surrogate is acting contrary to the patient's prior wishes or best interests because of involvement in suspected abuse or neglect, refer to subparagraph 8(4). Specific conditions must be met before such information may be disclosed without the patient's (or surrogate's) consent (see M-1, Pt. I, Ch. 9). Evidentiary material must be collected, retained, and safeguarded according to local VA medical facility policy.

e. **Research.** Participation in any human subjects research sponsored by VA, as well as any human subjects research conducted on VA premises, must meet requirements of current VHA policy (see M-3, Pt. I, Ch. 9, or superseding regulation and policy).

f. **Testing for HIV**

(1) **Testing for HIV.** This requires the prior informed and (written) signature consent of the patient (or surrogate) according to the procedures described in Paragraph 7 and Paragraph 8. In addition:

(a) Patients (or surrogates) who consent to testing for HIV must sign VA Form 10-0121 Consent for HIV Testing. The completed form must be filed in the patient's medical record.

(b) Testing must be accompanied by pre-test and post-test counseling.

(2) **Pre-test Counseling.** All elements of VA Form 10-0121 must be explained in detail by the practitioner, or professional counselor, during pre-test counseling. Pre-test counseling must include a description of the:

(a) VHA policy on non-discrimination in health care services for patients with HIV infection;

(b) Exceptions to the VHA policy for maintaining confidentiality of HIV test results including authorized disclosure to public health authorities or to a spouse and/or sexual partner;

(c) Health care services available in VHA;

(d) Meaning, sensitivity and specificity of the HIV tests;

(e) Potential social ramifications of a positive test result; and

(f) Measures to be taken for prevention of HIV transmission.

(3) **Documentation of Pre-test Counseling.** A signed progress note detailing the pre-test counseling must be entered into the medical record. The progress note must comply with subparagraph 7c, and include the details listed in subparagraph 9f(2) under pre-test counseling.

(4) **Post-test Counseling.** Post-test counseling must be adapted to both the test result and the particular needs of the individual patient.

(a) Negative Result. Counseling regarding a negative result must include, but need not be limited to:

1. Information about the accuracy of the test, if the patient is in a group at high-risk for HIV infection;

2. A discussion of the risks and benefits of re-testing; and

3. Reinforcement of risk-reduction behaviors.

(b) Positive Result. Counseling regarding a positive result must include, but need not be limited to:

1. Reinforcement of the availability of VHA health care services and community and public health resources;

2. A discussion of the advantages of notification of a spouse, other sexual partners, or others at risk of past or future exposure to HIV; and

3. Reinforcement of HIV transmission prevention measures.

(5) **Documentation of Post-test Counseling.** A signed progress note detailing the post-test counseling encounter must be entered into the patient's medical record. The progress note must comply with subparagraph 7c, and include the details listed is subparagraph 9f(4) under post-test counseling.

(6) **Confidentiality and Disclosure of HIV Status.** VA generated records that reveal the identity, diagnosis, prognosis, or treatment of VA patients related to HIV infection or Acquired Immune Deficiency Syndrome (AIDS) must be kept confidential. This information may not be released without the patient's special written consent, unless the disclosure is otherwise authorized by law. Unauthorized release of confidential information, such as HIV test results, may result in criminal penalties and/or substantial fines. ***NOTE:*** *Refer to M-1, Part I, Chapter 9, and consult the local Privacy Act Officer or Regional Counsel when questions arise.*

g. **Consent for Treatments or Procedures Delivered Via Telemedicine and Telehealth.** Informed consent is required for all clinical treatments and procedures, including those delivered via telemedicine and/or telehealth. For the purpose of informed consent, telemedicine and/or telehealth are considered to be part of the treatment or procedure, used to deliver health care services.

(1) All elements of the informed consent process apply to treatments or procedures delivered by telemedicine and/or telehealth.

(a) Specifically, practitioners need to provide information about telemedicine and/or telehealth that a patient would reasonably want to know, including:

1. The likely differences between receiving care delivered using telemedicine and/or telehealth technologies and face-to-face care.

2. The benefits and risks of using telemedicine and/or telehealth in the patient's situation, the likely benefits and risks associated with the alternatives to using telemedicine and/or telehealth to deliver the treatment or procedure in the patient's situation.

3. Whether the use of telemedicine and/or telehealth to deliver the treatment or procedure would be generally considered novel or unorthodox.

(b) Practitioners need to tell patients that they are free to choose among treatments or procedures that use telemedicine and/or telehealth and those that do not use telemedicine and/or telehealth, and that a prior consent for telemedicine and/or telehealth can be revoked without prejudicing the patient's access to future care or other benefits.

(2) **Documenting the Informed Consent Process.** Prior to undertaking any treatment or procedure using telemedicine and/or telehealth, the practitioner must obtain an informed consent and document the informed consent process in the medical record as described in subparagraph 7c.

(a) When the treatment or procedure that will be delivered via telemedicine and/or telehealth is low-risk and within commonly accepted standards of practice, a signature consent is not required.

(b) Treatments or procedures that meet one or more of the criteria listed in subparagraph 7c(2)(a), or are listed in Appendix A, require signature consent, whether provided via telemedicine and/or telehealth or in a face-to-face consultation. The degree of risk associated with some procedures may increase when telemedicine and/or telehealth is used. If the method used to deliver the care, i.e., telemedicine and/or telehealth, can be reasonably expected to produce significant discomfort to the patient or can reasonably be considered to have a significant risk of complication or morbidity, then the patient or surrogate must sign an authorized VA consent form. In addition, signature consent is required for the use of home telehealth.

10. REFERENCES

a. Title 38 United States Code (U.S.C.) § 7331, "Informed Consent."

b. Title 38 U.S.C. § 7332 "Confidentiality of certain medical records."

c. Title 38 Title 38 U.S.C. § 7333, "Nondiscrimination against alcohol and drug abusers and persons infected with the human immunodeficiency virus."

d. Title 38 CFR § 17.32, "Informed Consent."

e. Title 38 CFR § 16, "Protection of Human Subjects."

f. VA, VHA Handbook 1004.2, Advance Health Care Planning (Advance Directive).

g. VA, VHA Manual M-1, "Operations," Part I, "Medical Administration Activities," Chapter 5, "Patient Records."

h. Department of Veterans Affairs, Veterans Health Services and Research Administration Manual M-1, "Operations," Part I, "Medical Administration Activities," Chapter 9, "Release of Medical Information" (1990).

i. VHA Handbook 1004.3, "Do Not Resuscitate (DNR) Protocols Within the Department of Veterans Affairs (VA)."

j. VA, VHA Manual M-3, Part I, Chapter 9, "Requirements for the Protection of Human Subjects in Research."

k. Veterans Health Administration. VHA Six for 2006. (http://vaww.va.gov/6for2006/)

l. Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Comprehensive Accreditation Manual for Home Care. "Section R1, Common Home Care Standards for Rights and Ethics," 2001.

m. JCAHO, Comprehensive Accreditation Manual for Hospitals: The Official Handbook. "Section R1, Patient Rights and Organization Ethics." 2000.

n. JCAHO, 2000-2001 Comprehensive Accreditation Manual for Long-Term Care. "Section R1, Resident Rights and Organization Ethics," 1999.

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

p. Berg JW, Appelbaum PS, Lidz CW, and Parker LS, Informed Consent. Legal Theory and Clinical Practice. 2nd edition. New York, Oxford University Press, 2001.

TREATMENTS AND PROCEDURES REQUIRING SIGNATURE CONSENT

NOTE: *The following list is not exhaustive (see subpar. 7c(2) of the Handbook for a general description of treatments and procedures that require signature consent).*

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

    a. Acupuncture;

    b. Anesthesia (except for low-risk local anesthesia);

    c. Aspiration of body fluids through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis);

    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);

    f. Central vascular access device insertion (e.g., arterial line, Swan-Ganz catheter, percutaneous intravascular catheter (PIC) line, Hickman catheter);

    g. Electrocautery;

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

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

    j. Laser therapy;

    k. Oral surgical procedures (including gingival biopsy);

    l. Sterilization of reproductive capacity;

    m. Thoracotomy;

    n. Tracheostomy; and

    o. Transjugular intrahepatic portal stent (TIPS).

2. Blood product transfusion.

3. Dialysis (hemodialysis or peritoneal).

4. Electroconvulsive therapy.

5. Genetic testing.

6. Hazardous drugs (e.g., cancer chemotherapy, disulfiram, methadone for narcotic dependence, naltrexone).

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

8. Radiographic procedures to include:

a. Radiographic contrast agents in high-risk patients (e.g., those with prior allergic reactions, renal failure or other risk factors) for Computerized Axial Tomography CAT scans, cisternograms, intravenous pyelograms and other procedures; and

b. Ultrasound therapy (e.g., lithotripsy).

9. Home telehealth.