

**DEPARTMENT OF VETERANS AFFAIRS
NORTH TEXAS HEALTH CARE SYSTEM**

January 27, 2010
549/11

VANTHCS MEMORANDUM NO. 11-04

INFORMED CONSENT FOR CLINICAL TREATMENTS AND PROCEDURES

1. PURPOSE:

The purpose of this memorandum is to establish VA North Texas Health Care System (VANTHCS) policy on informed consent. It discusses the scope and key concepts related to patients' informed consent for clinical treatments and procedures and the related responsibilities of VANTHCS staff. VANTHCS 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.

2. POLICY:

A physician, dentist, or other practitioner with clinical privileges must inform a patient (or where appropriate, the patient's representative) of the name, nature, and details of a proposed diagnostic/therapeutic procedure or course of treatment, as well as the indications, expected benefits, associated risks, complications or side effects, reasonable and available alternatives, and anticipated results if nothing is done. This information must be provided in language understandable to the patient, or his surrogate decision maker. The patient must have the opportunity to ask questions; to indicate a comprehension of the information provided; to grant permission for performance freely, without fraud, duress, deceit or coercion; and the right to withhold or to revoke such permission without jeopardizing the right to future medical care and treatment.

3. PROCEDURES:

a. Definitions:

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

(2) Competence: Competence is a legal term which is assigned to a person by the judicial system. A physician, dentist, or other practitioner should therefore refrain from using the term "competent" or "incompetent" to describe a patient unless such term has been assigned to the patient by a court.

(3) Decision-Making Capacity: A clinical determination made by a practitioner, that a patient has the requisite capacities to make a medical decision. There are four major components to decision-making capacity:

understanding, appreciating, formulating, and communicating. Decision-making capacity includes the ability to understand and appreciate the nature and consequences of health care treatment decisions. This includes understanding the benefits and risks of the proposed treatment options, as well as any alternative treatment options.

(4) iMedConsent™: iMedConsent™ is a software package that supports electronic access, completion, signing, and storage of such documents as informed consent forms and advance directives. The software also includes an extensive library of patient education documents, drug information, and a wide selection of anatomical pictures and diagrams. These materials greatly improve the ability of staff members involved in patient education to access and distribute consistent and thorough information to patients. When electronic consenting is not feasible, VA Form 10-0431a "Consent for Clinical Treatment/Procedure" or VA Form 10-0431b "Consent for Transfusion of Blood Products" will be used. In this policy, except where specifically stated, the terms "signed" or "signature" will be used interchangeably to apply to both electronic and paper consent documents.

(5) Informed Consent: Informed consent implies a careful, thoughtful dialogue between the practitioner and the patient and, as such, is an integral part of quality medical care. However, the sensibilities of the individual patient must be considered. Undue emphasis on rare or unlikely complications should be avoided.

(6) Lack of Decision-Making Capacity: Lack of decision-making capacity is the inability to understand and appreciate the nature and consequences of health care decisions and inability to formulate and/or communicate decisions concerning health care. Patients who are incapable of giving consent as a matter of law; e.g., persons judicially determined to be incompetent, are deemed to lack decision-making capacity for the purpose of obtaining informed consent.

(7) Patient's Representatives: Patient's representative means an individual such as a health care agent, guardian, next of kin, organization, or other body legally authorized to consent to treatment of a patient who lacks sufficient understanding and/or legal capacity to give consent. Paragraph 3.I. governs obtaining consent from a patient's representative.

(8) Practitioner: Practitioner means any physician, dentist, or health care professional who has been granted specific clinical privileges to perform the treatment or procedure. Practitioner also includes medical and dental residents regardless of whether they have been granted specific clinical privileges and other health care professionals whose scope of practice agreements specifically permit them to obtain informed consent and who are appropriately trained and authorized to perform the procedure or provide the treatment for which the consent is being obtained.

(9) Risk: 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.

(10) Signature Consent: Signature consent refers to the patient's (or surrogate's) signature on a VA-authorized consent form.

(11) Universal Protocol: Procedure utilized at VANTHCS for preventing "wrong site, wrong person, and wrong procedure".

(12) 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 10-431a, Consent for Clinical Treatment or Procedure <http://vaww4.va.gov/vaforms/medical/pdf/10-0431a-fill.pdf> and VA Form 10-431b, Consent for Transfusion of Blood Products <http://vaww4.va.gov/vaforms/medical/pdf/10-0431b-fill.pdf> are authorized if :

- (a) The patient declines to use the electronic signature pad, or
- (b) There is a temporary system failure that prohibits proper use of the iMedConsent™ software program, or
- (c) The patient is giving consent by telephone or fax, or
- (d) The use of the equipment that supports the iMedConsent™ software program would introduce infection control issues (e.g., the inability to adequately disinfect the signature pad used for a patient in isolation precautions).
- (e) It is an emergency and the use of iMedConsent™ would delay the procedure or treatment so as to harm the patient.

b. The Informed Consent Process

(1) Informing the Patient: During the informed consent process the practitioner must:

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

(1) For treatments that are low risk and within broadly-accepted standards of medical practice, it is acceptable to obtain oral consent for the entire treatment or procedure without discussing each 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).

(2) Information about certain tests that are particularly

sensitive and may have consequences that the patients might reasonably want to avoid. These tests include but are not limited to specific tests to identify illicit drug use, alcohol intoxication, HIV, Hepatitis C, Hepatitis B, Methicillin-Resistant Staphylococcus aureus (MRSA), sexually transmitted diseases, and heritable genetic abnormalities. For these tests, practitioners must obtain specific oral consent and must document that in the patient's electronic health record.

- (b) Describe the recommended treatment or procedure in language that is understandable to the patient.
- (c) Give a clear description of the patient's condition or diagnosis that relates to the recommended treatment or procedure.
- (d) Describe the name, nature and details of the recommended treatment or procedure, including the likelihood of success of the recommended treatment for that patient. Use no abbreviations, unless you define them in the consent.
- (e) Describe the expected benefits, known risks, alternative treatments and procedures, including the option of no treatment, potential emergency responses to known complications of the treatment or procedure that the patient may wish to forego (e.g., blood transfusion for bleeding during the procedure).
- (f) Provide written educational material to patients recommended for HIV testing (Attachment A).

c. Documenting the Informed Consent Process: The fact that the patient has been provided information and counseling, and has consented to the proposed procedure or treatment, should be documented in the patient's medical record. Informed consent should include the following elements:

- (1) The practitioner's assessment of whether the patient has decision-making capacity.
- (2) The name of the practitioner immediately responsible for the performance, and, if applicable, the supervision of the procedure or treatment.
- (3) A brief description of the recommended treatment or procedure.
- (4) The fact that relevant and material aspects of the procedure or treatment, the indications, risks, benefits, and alternatives have been discussed with the patient in understandable language.

- (5) The fact that the patient had the opportunity to ask questions.
- (6) The fact that the patient freely consented to the procedure/treatment without duress or coercion.
- (7) The date and time the discussion took place and if consent was given.
- (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 obtaining the consent and writing the note (including their legibly written name).
- (10) Signatures do not need to be witnessed, except when the patient's or surrogate's signature is indicated on the form by an X. In that case, two adult witnesses are required to sign, affirming that the witnesses saw the patient or surrogate and the practitioner sign the form. **NOTE:** *If an individual cannot physically document consent, a member of the treatment team may sign on the patient's behalf and document the circumstances of the signature in a progress note. The signing health professional's signature must be witnessed by two adults.*
- (11) 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 which would alter the diagnostics treatment plan, the consent is rescinded automatically and the process must be documented. In the event that consent is refused or revoked, the note will include all of the above plus the refusal or revocation of consent, and the fact that the consequences of such refusal or revocation were discussed with the patient.
- (12) Signed VA-authorized consent forms are filed in the patient's electronic medical record, either by scanning in the VistA Imaging system or through the iMed Consent progress note.

d. Treatments and Procedures That Require Signature Consent:

- (1) Prior to providing certain procedures or treatments, specific documentation of the consent must be completed in detail.
- (2) The patient's signature consent must be obtained for treatments and procedures that:
 - (a) Can reasonably be expected to produce significant pain or discomfort to the patient.
 - (b) Can reasonably be expected to produce significant pain or

discomfort to the patient so that sedation, anesthesia or narcotic analgesia is required.

(c) Can be reasonably considered to have a significant risk of complication or morbidity.

(d) Require injections of any substance into a joint space or body cavity.

(e) Are included in the Attachment B.

e. Multiple Visits or Procedures: When the proposed treatment involves multiple visits or procedures it is not necessary to repeat the informed consent discussion for each new treatment or procedure provided that the original consent encompassed all the treatments and procedures and:

(1) There is no significant deviation from the treatment plan as originally outlined to the patient.

(2) No new or unusual problems or complications have arisen which would require alteration of, or deviation from, the original treatment plan.

f. Refusal of Consent: The patient has the right to refuse or withhold consent. A reasonable amount of time must be given to permit consideration of the response. If consent is refused, the consequences of such refusal must be carefully explained by the practitioner and that fact documented in the medical record. Discussion with responsible and concerned family members, with the patient's concurrence, is encouraged to keep them apprised of treatment plans for the patient. Such involvement will often permit family members to alleviate any undue anxieties which may have been the reason that a patient refused to give consent for a necessary procedure/treatment. Where refusal to consent is seen to constitute a hazard to others, the matter should be called to the attention of the Chief of Staff. If consent is refused for religious reasons, this should be thoroughly documented in the progress notes.

g. Exception for Emergency Situations: The practitioner may proceed to provide the necessary medical care without obtaining consent when all of the following three conditions are met:

(1) If for any reason the patient is unable to consent to a procedure/treatment.

(2) Immediate medical care is necessary to preserve the life or prevent serious impairment of the health of the patient or others.

(3) The treating practitioner determines that the patient has no surrogate, or waiting to obtain consent from the patient's representative would result in a

delay which would materially increase the hazards to the life or health of the patient or others.

In such a situation, the patient's consent is implied by law. A dated and signed progress note documenting this imminent danger and the decision to proceed must be written by the appropriate practitioner. If time permits, reasonable attempts should be made to contact the patient's representative to obtain consent. If time does not permit, or the representative is not available, such individual(s) should be contacted as promptly as possible after the procedure/treatment to explain what was done, the indications for it, and the outcome. The signature of the Chief of Staff is required in cases where diagnostic or therapeutic efforts are based upon an implied consent. This signature may be obtained after the clinical intervention, when necessary.

h. Consent from Patient's Representative:

(1) Consent from the Patient's Surrogate Decision-Maker:

(a) Substituted Judgment: In non-emergency situations, consent must be secured from the patient's surrogate when the patient lacks the capacity to make health care decisions.

(1) The practitioner, in consultation with the chief of service or Chief of Staff, may determine after appropriate medical evaluation that the patient lacks decision-making capacity and is unlikely to regain it within a reasonable period of time. The practitioner must document this determination in the medical record in a signed and dated progress note.

(2) Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the patient lacks decision-making capacity is based on mental illness. 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.

(3) Disclosures required by this policy to be made to the patient by the practitioner, must be made to the patient's surrogate to the extent permitted by law.

(4) If feasible, the practitioner must explain the proposed treatment or procedure to the patient even when the surrogate gives consent.

(b) Disagreement between Surrogates at the 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 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 may consult the Ethics Consultation Service or Regional Counsel.

(c) Priority: Informed consent must be obtained from individuals in the following priority:

(1) Health Care Agent: The health care agent is the individual named in a Durable Power of Attorney for Health Care (DPAHC) executed by the patient while the patient had decision-making capacity. The health care agent acts on the patient's behalf to make health care decisions, including the use of life-sustaining treatment when the patient is unable to provide consent (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)).

(2) Legal Guardian or Special Guardian: A legal guardian or special guardian is a person appointed by a court of appropriate jurisdiction to make decisions for an individual who has been judicially determined to be incompetent by a court of law. Under VHA policy, legal guardians and special guardians have the same authority to make healthcare 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.*

(3) Next-of-Kin: The next-of-kin is a relative (18 years of age or older) who may act as surrogate for the patient in the following order of priority; spouse, child, parent, sibling, grandparent, grandchild.

(4) Close Friend: A "close friend" is considered any person 18 years or older (including a relative not listed above) who has shown care and concern for the patient's welfare and is familiar with the patient's activities, health, religious beliefs, and values. The close friend must present a signed, written statement (to be filed in the medical record) that describes (with specific examples) that person's relationship to and familiarity with the patient. Social Work Service must verify, in a signed and dated progress note, that these requirements have been met.

(5) No Surrogate Available: If none of the surrogates are available, the practitioner may contact Regional Counsel for assistance in obtaining a guardian for health care decisions or may follow the procedures outlined as follows.

(2) Consent for Patients Who Have No Surrogate:

This paragraph sets out an alternative process for decision-making on behalf of patients without surrogates. This process takes place primarily within the medical facility.

(a) Treatments and Procedures that Do Not Require Signature Consent: Low risk procedures or treatments that are within broadly accepted standards of medical practice do not require the patient's signature consent. As part of good medical practice, the practitioner must discuss these measures with the patient. Even if the patient lacks decision-making capacity, the practitioner must attempt to explain the nature and purpose of the proposed treatment. The practitioner must indicate in a signed and dated progress note whether it was possible to communicate with the patient and if the patient appeared to understand.

(b) Treatments and Procedures that Require Signature Consent: This category includes treatments and procedures that require signature consent, but do not involve withholding or withdrawal of life-sustaining treatments. The following information must be documented in the medical record:

(1) Certification by the attending physician, including a statement by Social Work Service, that after reasonable inquiry they have determined that the patient has not designated a health care agent through a DPAHC and has no legally appointed guardian or available and willing next-of-kin or close friend to act as a surrogate who can be located.

(2) The attending physician indicates participation in and concurrence with the treatment decision in a signed and dated progress note in the medical record.

(3) The Service Chief, or designee, provides written concurrence with the treatment decision in the patient's medical record.

(c) Quality Assessment Review: Patients who lack decision-making capacity and have no surrogate are an especially vulnerable class of patients. Each VA medical facility must develop a mechanism to review compliance with the preceding decision-making procedures.

i. Special Situations with Specific Consent Requirements:

(1) Unusual or Extremely Hazardous Treatments or Procedures: No patient will undergo any unusual or extremely hazardous treatment or procedure; e.g., that might result in irreversible brain damage or sterilization, except as follows:

(a) Before treatment is initiated, the patient must be given adequate opportunity to consult with independent specialists, legal counsel, or other interested parties of the patient's choosing. The patient'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, legal guardian, or patient advocate).

(b) If the patient lacks decision-making capacity, consent must be obtained from the patient's surrogate. The surrogate must be permitted to consult with independent specialists, legal counsel, or other interested parties concerning the proposed treatment or procedure. Before treatment is initiated, a multi-disciplinary committee, appointed by the Director, must review the surrogate's decision to assure it is consistent with the patient's wishes (or best interest, if the patient's wishes are not known). The committee functions as the patient's advocate and may not include members of the treatment team. The committee must submit its findings and recommendations in a written report to the Director. The Director may authorize treatment consistent with the surrogate's decision or request that a special guardian for health care be appointed to make the treatment decision.

(c) If there is no available surrogate, the practitioner may follow the procedures outlined in paragraph 2.b., or request that a special guardian be appointed to make health care decisions for the patient. NOTE: Contact Regional Counsel for assistance.

NOTE: The practitioner must document compliance with these procedures in a signed and dated progress note.

(2) Forced Administration of Psychotropic Drugs: Administration of psychotropic medication to an involuntarily committed patient against the patient's will must meet Constitutional due process requirements. The practitioner must document compliance with the following procedures in a signed and dated progress note.

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

(b) Any recommendation to administer or continue psychotropic medication against the patient's will must be reviewed by a multi-

disciplinary panel appointed by the Director for this purpose. The panel must include a psychiatrist or a physician who is experienced in prescribing psychotropic medications and managing serious mental illness. The panel functions as the patient's advocate and may not include members of the treatment team. The panel must submit its findings and recommendations in a written report to the Director. The Director must review recommendations and may concur, non-concur, or consult Regional Counsel. The Director's decision must be documented in the patient's electronic medical health record. Administration of psychotropic medications contrary to the patient or surrogate's wishes may only be undertaken with the concurrence of the Director.

(c) Continued therapy with psychotropic medication must be reviewed every 30 days by the prescribing provider and the results documented in the patient's electronic health record.

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

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

(3) Assessment of the patient for Suspected Abuse or Neglect: Information and/or other evidentiary material(s) collected during the diagnosis and treatment of a patient who is the suspected victim of abuse or neglect could be used for future prosecutions. The practitioner must assure that the proper consent for diagnosis and treatment is obtained from the patient or surrogate and appropriately documented in the medical record. There are specific conditions that must be met before such information may be disclosed without the patient's consent. Evidentiary material released by the patient will be collected, retained, and safeguarded according to local VA medical facility policy.

(4) Research: This memorandum does not apply to consent for use of investigational drugs and treatments or procedures that involve research.

j. 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, 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 not be released without the patient's special written consent, unless the disclosure is otherwise authorized by law. VA Form 10-5345, Request For and Authorization to Release Medical Records, must be signed if the patient wishes to have this information shared with the patient's surrogate in the event that the patient loses decision-making capacity. **NOTE:** *Consult the local Privacy Officer or Regional Counsel if you have any question about the release of this type of information.*

k. 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, and 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 surrogates) explicit informed consent and that consent must be documented according to procedures as outlined in subparagraph (3). 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.

(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 a provider who does not have a personal relationship with the exposed employee (e.g., friend, family member, former spouse) and, whenever possible, by a provider 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.

l. Surrogate Consent by Mail, Fax, Telephone, or E-mail. Ideally, the informed consent discussion and signature consent (where required) is 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 (VA Form 0431a or VA Form 10-0431b). 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 placed in the patient's electronic health record.

While a faxed copy of a completed consent form (VA Form 0431a or VA Form 10-0431b) signed by the surrogate is adequate to proceed with treatment, the surrogate must agree to submit the original form that the surrogate signed.

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

(a) The practitioner must:

(1) Call the proposed surrogate and identify and verify the parties on the line. **NOTE:** *This responsibility may be delegated to a Medical Administration Service representative.*

(2) Ask the surrogate for permission to record the conversation.

(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.

(5) Document the process in CPRS by filing a typed transcript of the entire discussion with the date and time of the call.

(3) **Consent by E-mail.** Signature consent by e-mail is not permitted, even where Secure Messaging Systems are available.

4. **RESPONSIBILITIES:**

a. The Practitioner:

(1) The practitioner who obtains the informed consent for the treatment or procedure must follow the processes established in this policy.

(2) The practitioner who will be performing the particular procedure/treatment will ensure that the informed consent was obtained, even when the practitioner performing the treatment or procedure is not the same person who obtained the consent.

b. The Chief of Staff will be responsible for seeing that this memorandum is distributed to and complied with by VANTHCS practitioners.

5. **REFERENCES:** VHA Handbook 1004.01 Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.

6. **RESCISSION:** VANTHCS Memorandum No. ET-3, "Informed Consent", dated March 12, 2008.

Joseph M. Dalpiaz
Director

Attachments

Distribution "A"



Information about HIV Testing

What is the HIV test?

This test can tell if you have human immunodeficiency virus (HIV), the virus that causes AIDS. HIV weakens the body's immune system. When the immune system is damaged so much that the person can get serious infections or cancers this is called AIDS. People infected with HIV may have no symptoms for many years. Even without symptoms damage to the immune system happens and infected people can still pass the virus to others.

The test is usually done using blood taken from a vein with a needle. Sometimes it can be done using blood from sticking your finger or fluid from inside your mouth (oral fluid). If your first test is done with oral fluid or blood from a finger stick and is positive we will take blood from a vein for a second test to confirm the results.

Why does VA want to test me for HIV?

Testing is recommended for all patients, even those who do not think they may have been exposed to HIV. For some patients who have had a possible exposure or who have symptoms suggesting they might have HIV infection repeat testing may be recommended.

How will the HIV test help me?

If you have HIV, the sooner you know, the sooner you can take steps to stay healthy. There are effective treatments that help people with HIV live longer and healthier lives. If you learn you have HIV, you can take steps to avoid spreading the virus to others. You can get care for HIV at VA. Your HIV test result will not affect your VA care or eligibility for VA benefits.

What are the possible risks of this test?

- You may feel sad, depressed, angry or anxious if you learn you have HIV. This is natural. If these feelings are severe, your provider can refer you to someone at VA who can help you.
- If other people find out about the HIV diagnosis, some people may treat you unfairly.

Protecting your privacy

VA will not give your HIV test results to anyone except your caregivers or providers unless you give permission in writing except in these SPECIAL CASES

- Within VA for medical care
- With a VA health care provider or employee in case an employee comes into contact with your blood, such as by an accidental needle-stick
- Within VA if the VA needs the information to see if you qualify for VA benefits;
- With a specific health care provider in an emergency if the information is required to provide you with medical care
- To report to public health authorities
- If ordered by a court of law
- If the Department of Defense requests it (to use for treatment or benefits);
- If Congress requests it for VA program oversight (your name will not be used)

- For VA-approved scientific research (your name will not be used)
- To evaluate patient care
- If you tell a VA provider that you have unprotected sex with someone and will not tell them your HIV status the provider can tell them to protect their health.

What happens if I refuse to have this test? You have the right to refuse to have this test done. If you refuse to have this test, your health care providers may not have all the information needed to take the best care of you.

What are the alternatives to having this test done in VA?

You can have an HIV test done outside VA. If you have a test done outside VA you will have to pay any cost yourself. In some places you can get an HIV test done anonymously (without giving your name.)

What HIV test results mean: When testing is completed the result is reported to your provider. Your provider will tell you the result. Possible results are:

Positive : result means that you have an HIV infection and you can pass it to others.

Negative: result means either you do not have HIV or got it so recently that your body has not had time to make enough antibodies to be seen by the test. If your result is negative but other things seem to point to HIV as a possibility you should have the test repeated later.

Indeterminate : means that the test did not show whether or not you have HIV. This could happen if you have another medical condition that interfered with the test or have been infected recently. If you have an indeterminate HIV test result, you need to have an HIV test repeated at a later date to find out for sure if you have HIV.

What everyone needs to know about how HIV spreads from person to person.

- People spread HIV by:
 - o Unprotected (without a condom) sexual contact.
 - o Sharing needles or "works" (cookers and other things used to prepare drugs for injection) during drug use.
 - o From an HIV infected woman to her baby during pregnancy, labor, or breastfeeding
- You can reduce risk by:
 - o Not having sex
 - o Using a condom every time you have sex.
- For pregnant women there are drugs that will improve your health and reduce the risk to the baby
- You can get HIV any time you inject drugs and share needles or works. .You can reduce the risk by:
 - o Not injecting drugs
 - o Never sharing needles or works.

You should find out how and when you will get your HIV test results.

If your HIV test is positive, you can still get care at VA. Your provider may refer you to another medical professional for follow-up care.

From VA Public Health Strategic Planning Group, August 2009; reviewed for use by VANTHCS ID, October 2009

TREATMENTS AND PROCEDURES REQUIRING SIGNATURE CONSENT

1. Surgical or invasive procedures, including but not limited to:
 - a. Any procedure done within an operating room
 - b. Acupuncture
 - c. Aspiration of body fluids or injection of therapeutic or diagnostic agents through the skin or into a body cavity (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, 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., angiography);
 - j. Photocoagulation;
 - k. Oral surgical Procedures (including gingival biopsy);
 - l. Sterilization of reproductive capacity
 - m. Thoracostomy;
 - n. Tracheostomy;
 - o. And 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 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 iMedConsentTM.
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).
11. Phototherapy 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 (medical-legal) Examination.