Frequently Asked Questions
Informed Consent Requirements for HIV Testing

Updated July 15, 2015

1. Is there a requirement to provide written educational materials about HIV to patients before testing?

No. On May 5, 2015, VHA Directive 1113 Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities was issued. With this Directive, and through a June 5, 2015, DUSHOM memo, VHA waived the requirement (in VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, paragraph 13.a.(7)) that providers must give written educational materials to patients as part of the oral informed consent process for HIV testing. However, clinicians are encouraged to provide materials if they believe that some patients would find it helpful to have them. NOTE: Facilities can work with their clinical application coordinators to remove language about this requirement from local HIV clinical reminders and order sets.

2. What is specific oral informed consent, and are practitioners required to obtain it from patients before administering an HIV test?

“Specific oral informed consent” is the consent and documentation process for tests, including the HIV test, specified in Handbook 1004.01 Informed Consent for Clinical Treatments and Procedures that are “particularly sensitive and may have consequences that the patient might reasonably want to avoid.” Examples of consequences are that test results may be reported to public health authorities, in a court of law; or, the results may adversely affect someone’s ability to be employed or insured. Administering such tests requires the specific consent of the patient.

Yes, practitioners must obtain specific oral informed consent from patients before ordering an HIV test. Signature consent is not required.

3. How must the practitioner document the patient’s oral consent for an HIV test?

The patient’s oral consent to the HIV test must be specifically documented in the health record with a statement such as "patient consents to HIV testing."

4. Is specific oral informed consent required for tests such as Western blot, HIV-RNA, or Branching DNA to help manage patients who are already known to have HIV disease?

No. For patients who already have an HIV+ diagnosis, it is sufficient to obtain the patient’s oral consent for the treatment plan that includes testing to monitor the disease.

5. If a patient initiates the request for an HIV test, do practitioners still need to go through the informed consent process?

Yes. Practitioners must conduct the informed consent with a patient even if the patient initiates the request for an HIV test. Practitioners have an ethical obligation to ensure that patients receive and understand information about the risks, benefits, and alternatives of
HIV testing as a basis for the decision about the test. The informed consent process is the way that the practitioner communicates this information and ensures the patient’s understanding before the test is ordered.

6. **Who must obtain informed consent for an HIV test?**

Policy specifies that informed consent must be obtained by the *practitioner*, defined in VHA Handbook 1004.01 *Informed Consent for Clinical Treatments and Procedures* (paragraph 3, page 2), as:

- **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 purposes 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.

Based on this definition, the phrase “to perform the treatment or procedure” means to order an HIV test. Although other members of the treatment team may assist in the informed consent process, only 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 order the test may obtain the patient’s oral informed consent by ensuring that the patient has been appropriately informed, understands and consents to the test.

7. **How long is a patient’s oral consent to an HIV test valid?**

The relevant VA regulation (38 CFR 17.32) and policy (1004.01) are silent on the length of time that an oral consent is valid. As a rule of thumb, it makes sense to use the 60-day timeframe since it is familiar (based on signature consent requirements for various treatments and procedures) and also based on the common sense expectation that beyond 60 days, a patient may have forgotten the details that were the basis of the consent. Because many workflows involve obtaining consent for the test at the current appointment for labs that may be drawn at the next appointment, it is appropriate to specify in the documentation that the patient gave consent to have an HIV test at their next appointment, up to 12 months. This would clearly document that the patient not only gave informed consent for the HIV test but also for the test to be administered in the specified time period.

8. **May a single informed consent be obtained for a series of HIV screening tests?**

Yes, if repeat HIV screening is part of the treatment plan and the following conditions are met, as indicated in VHA Handbook 1004.01 *Informed Consent for Clinical Treatments and Procedures*, paragraph 4c:

- VHA does not recognize “general” or “blanket” consent for medical treatment, but requires the patient’s separate 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 a new consent 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.

In the case of screening tests for HIV, examples of when consent may be obtained for a series of tests include:

a. A patient's treatment plan includes pre-exposure prophylaxis and requires repeat screening; or
b. A patient has an indeterminate HIV test result and repeat HIV screening is needed to determine whether or not the patient has become HIV-positive; or

In these cases, when a series of HIV tests is part of the treatment plan, the practitioner must discuss the anticipated series with the patient in the initial informed consent and document this in the record. If the clinical circumstances or treatment plan change during the series, a new consent is required. Also, because it is likely that the patient's clinical status will change, it is prudent to conduct the full oral informed consent process with the patient again in 12 months. The patient should be told each time an HIV test is being administered and given the opportunity to take or refuse the test.

9. If the health record suggests that an HIV test was administered after a patient refused the test, should I conduct a clinical disclosure to let the patient know?

If the health record shows that a patient refused an HIV test, but the test was administered anyway, it could be a case of incomplete documentation. In such a case, local staff should review the patient’s record to determine if there is any evidence that specific oral informed consent was obtained before the test. Then, if it appears that a patient was tested despite his or her refusal, a clinical disclosure should be conducted. See VHA Handbook 1004.08, Disclosure of Adverse Events to Patients and contact your local ethics consultation service for more information.

10. What should the practitioner do if the patient is unable or unwilling to give oral consent for a recommended HIV test?

If the patient is unable to consent because he or she lacks decision-making capacity, then the practitioner should conduct the informed consent process with the patient’s surrogate. If the patient is unwilling to consent to an HIV test that a practitioner believes is necessary, the practitioner should explain the importance of the HIV test and the reason for the recommendation. Patients have the right to accept or refuse any medical treatment or
procedure, therefore, the practitioner may neither force the patient to have the test nor order the test without the patient’s consent.

11. Even though signature consent for HIV testing is not required, may I obtain signature consent to administer an HIV test?

Although tests conducted to identify HIV disease are sensitive, this test does not meet the risk threshold for the signature consent requirement. In addition, the signature consent process requires a special workflow to obtain signatures and the risks associated with the HIV test are not sufficient to warrant the process that would be required to provide the practitioner and patient or surrogate with access to iMedConsent™ and the signature pad.

12. Since HIV is a sexually-transmitted disease (STD), does obtaining the patient’s informed consent for “STD screening” satisfy the requirement to obtain the patient’s informed consent for HIV screening?

No. Unless the informed consent discussion includes specific information about the HIV test, then the patient has not given specific oral informed consent for the HIV test. The only way to ensure that a patient understands what is encompassed in STD testing and has sufficient information about STD tests to consent to them is for the practitioner to ensure that the patient receives and understands information about the risks, benefits, and alternatives of the tests. The informed consent process is the way that the practitioner communicates this information and ensures the patient’s understanding before the test is ordered. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, paragraph 13a1(b) specify the requirements for informed consent for HIV testing (also, see FAQ #1).

Please check for updates to this FAQ document on the National Center for Ethics in Health Care’s website: http://www.ethics.va.gov/policy.asp.

For specific ethics concerns about informed consent for HIV, please contact your local Ethics Consultation Service. For questions regarding this FAQ document, please email vhaethics@va.gov or call 202-632-8457.