

September 6, 2002

## CONSENT FOR HIV TESTING FOR PATIENTS WHO LACK DECISION-MAKING ABILITY

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive provides information regarding VHA policy in obtaining consent for Human Immunodeficiency Virus (HIV) testing for patients who lack decision-making ability.

**2. BACKGROUND:** Recently there has been extensive discussion concerning HIV testing of source patients after occupational exposures, particularly when the source patient lacks decision-making ability. This Directive clarifies some of the concerns that have been raised.

a. HIV testing is defined to include any laboratory test that would lead to a diagnosis of HIV (antibody, antigen, viral load, ribonucleic acid (RNA), CD4 measurement, etc.).

b. Requirements for written informed consent for HIV diagnostic testing are based on Federal statutes enacted to ensure that testing is voluntary and is based on a full disclosure of the risks as well as the benefits of diagnosis. While these statutes were based on assumptions about prognosis and treatment that have changed over time, the basic concepts of voluntary testing and written informed consent are still codified in law and widely viewed to be fair and ethical.

c. Current standards of care in the case of occupational exposure to blood or body fluids potentially contaminated with HIV include post-exposure prophylaxis with anti-viral medications when the exposure is of a type believed to convey significant risk of infection. Since it is important to begin post-exposure prophylaxis as quickly as possible, prophylaxis decisions are frequently made without knowledge of the source patient's HIV antibody status. If the source patient can be determined to be uninfected, prophylaxis may be discontinued thereby relieving the exposed individual of anxiety, as well as the potential side effects of anti-viral drugs. If the source patient is infected, or if the source patient's status cannot be determined, then prophylaxis is continued for 4 weeks. **NOTE:** *If the source of an occupational exposure is a patient who lacks decision-making ability, current VHA policy for designating a surrogate exists and needs to be used. VHA employees who have been exposed in these situations should seek assistance from an Employee Health Provider or other designated clinician familiar with guidelines for post-exposure evaluation and treatment.*

d. Special concerns arise in the relatively rare circumstances in which a source patient's HIV status cannot be determined through voluntary, informed testing. These include the following:

- (1) Competent source patients who refuse to be tested.
- (2) Source patients who have died or cannot be contacted.
- (3) Patients who lack decision-making ability.
- (4) Situations in which the identity of the source patient cannot be determined.

e. Years of experience both inside and outside of the Department of Veterans Affairs (VA) suggest that the instances in which a source patient's HIV status cannot be determined are rare.

**THIS VHA DIRECTIVE EXPIRES SEPTEMBER 30, 2007**

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Few patients, or their surrogates, refuse consent for testing when appropriate counseling and information are provided. In the small number of cases in which a source patient refuses, or the source patient cannot be identified, (such as injury from a needle that has been improperly discarded) employees may decide to take a full course of post-exposure prophylaxis.

f. Despite the rarity of source-patient HIV status uncertainty, these situations generate substantial concern among health care workers who may be exposed and those who counsel and treat them. No systematic data exist regarding the frequency, nature, or consequences of occupational exposures in which the HIV antibody status of the source patient cannot be determined. The Office of Public Health and Environmental Hazards (13), is developing a formal surveillance protocol to evaluate this problem. The goal is to determine the true frequency of the problem, identify possible solutions, and ensure that all appropriate and necessary steps are undertaken.

g. The degree of anxiety provoked by potential exposure to HIV cannot be underestimated, and VHA health care providers deserve compassionate and professional advice in these difficult circumstances. The need to balance the rights and best interests of patients with staff safety as health care providers is not unique to HIV. The procedures currently available to deal with the rare situations described in the preceding paragraphs attempt to maintain that balance despite the understandable fears associated with exposure to serious pathogens. *NOTE: The Office of Public Health and Environmental Hazards (13), is able to assist with the interpretation and execution of these policies and procedure; facilities are encouraged to contact (13) whenever difficult situations develop.*

**3. POLICY:** It is VHA policy that all HIV testing requires Voluntary informed consent from the patient or an appropriate surrogate, and that existing guidelines for obtaining consent from patients who lack decision-making ability apply to situations of possible exposure to HIV; the exposure of health care workers to HIV continues to be an important safety issue.

**4. ACTION:** It is the responsibility of the medical center Director to ensure that:

a. Blood collected for other purposes is not used to test for HIV without the consent of the source patient or the source patient's surrogate.

b. HIV test results already in the source patient's medical record may be accessed by an Employee Health clinician for the purpose of providing recommendations to an exposed employee. The Employee Health provider may disclose this information to the exposed individual to the extent that is necessary for the employee to make an informed choice about post-exposure prophylaxis. Except for this specific situation, disclosure of HIV test results to anyone other than medical professionals responsible for the patient's care without prior written consent for release of information is not allowed (except for some forms of disclosure to state and local health departments, law enforcement agencies, and Congress or its agencies).

c. If the source patient is incapacitated, incompetent, or comatose, a legal guardian or designated surrogate may provide written consent for testing..

(1) The procedure for identifying a surrogate is described in detail in VHA Handbook 1004.1. In the case of decisions about post-exposure prophylaxis, consideration needs to be given to the expected duration of the patient's incapacitation when deciding whether to seek consent from a surrogate.

*NOTE: If the practitioner determines that the patient is likely to regain decision-making capacity within a reasonable period of time, the practitioner needs to wait until the patient's decision-making capacity returns; and then undertake the informed consent process with the patient. If the practitioner determines that the patient is unlikely to regain decision-making capacity within a reasonable period of time, an authorized surrogate needs to be sought.*

(2) VHA Handbook 1004.1 also describes a process whereby the treating facility, in the person of the Chief of Staff, may bypass the informed consent process when there exists a medical emergency that could result in loss of life or permanent disability without immediate medical treatment. Post-exposure prophylaxis is readily and frequently initiated without knowledge of the source patients' status and delay until a surrogate can be identified or the patient regains competency does not create additional risk. Therefore, authorization for HIV testing by the Chief of Staff is not permitted without the patient's consent or that of an appropriate surrogate.

d. Appropriate programs are established for the prevention and management of occupational exposure to blood and other potentially infectious materials.

## 5. REFERENCES

- a. General Counsel Advisory Opinion VADIGOP 6-8-88.
- b. General Counsel Advisory Opinion VAOPGCADV 13-2002.
- c. VHA Handbook 1004.1.

**6. FOLLOW-UP RESPONSIBILITY:** The Director, HIV National Program Office, with the Public Health Strategic Health Care Group (132/13B), is responsible for the contents of this Directive. Questions may be referred to 202-273-8296.

**7. RESCISSIONS:** None. This VHA Directive expires September 30, 2007.

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Under Secretary for Health

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