

Investigator Guidance Series

University of Utah Institutional Review Board

HIV ANTIBODY TESTING

Description

This policy covers HIV antibody testing as a condition of entry into a research study, or as part of the research study itself. HIV antibody testing and AIDS research requires special precautions to insure that risks to subjects are minimized and confidentiality is guaranteed. HIV antibody testing is permitted, as set forth in the regulations. The costs of HIV/AIDS testing must be borne by the research study and may not be charged to the patient, insurance company or other third party payer.

The investigator needs to complete the HIV checklist at the time of submission to the IRB. The Investigator's protocol needs to address the following items and provide an HIV Testing Checklist. This checklist is completed in the ERICA online submission system as a part of the New Study Application.

Justification: Investigators must provide a brief justification for the testing (e.g. new knowledge, protection of others, etc.).

Counseling: The process of informed consent to HIV antibody testing is especially sensitive. Subjects must be informed of the potential psychological, economic, legal, and medical significance of the test results prior to testing. The protocol must address how this issue will be handled and the consent form should contain this information. Subjects must also be offered counseling before undergoing testing.

Data Security: Researchers must inform subjects in the consent form about the planned disposition of HIV antibody test results. Personally identifiable results of HIV antibody testing must be destroyed unless the IRB authorizes otherwise. If personally identifiable test results must be retained for study purposes, the investigator should provide a justification to the IRB, together with an explanation of how data security will be maintained. Data must be kept confidential and may not be made available to anyone except federal or institutional authorities with the right to examine research records, the research sponsor, the investigator and others authorized in connection with the research project, or the identified subject or designee. Investigators who undertake HIV antibody testing or AIDS research are responsible for maintaining adequate data security. Normally it will suffice to store data in locked cabinets, accessible only to the investigator and other authorized people.

Communication of Test Results: HIV antibody test results that are associated with personal identifiers must be communicated to the subject, with appropriate counseling and partner notification services, by either the investigator or arrangements made by the investigator with the subject's regular health provider. The protocol must address how this will be done. There are three exceptions to this requirement:

- 1) Compelling and immediate reasons that justify not informing a particular individual of HIV seropositivity, such as likelihood of suicide. The reasons must be documented and the case reported to the IRB, without identifying the individual.
- 2) Circumstances in which extremely valuable knowledge might be gained from subjects who might refuse to learn their HIV antibody results, an exception may be proposed to the IRB. In proposing such an exception, the investigator must demonstrate that: (a) research subjects will be informed of their risk of infection; (b) research subjects will receive risk reduction counseling whether or not they receive their test results; (c) there is good reason to believe that a requirement for test result notification would significantly impair collection of study information. The IRB will retain the right to ask for periodic assessment by the investigator of the risk/benefit ratio to the individuals, their partner/s and society such that the IRB can determine if

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justification exists for the continuation of the research.

3) Studies conducted at foreign sites should be carefully evaluated to account for cultural norms, the health resource capabilities and official health policies of the host country. If a research protocol review is involved, the reviewing IRB must consider if any modification to the policy is significantly justified by the risk/benefit evaluation of the research. The IRB might wish to seek advice, e.g., local public health experts, in the evaluation of these projects.

State Law & Mandatory Reporting: Investigators are cautioned that a diagnosis of AIDS or seropositivity may have serious legal and financial consequences for research subjects. In Utah, a positive test result for HIV or AIDS must be reported to the Utah State Health Department or the local health department where the patient resides. In rare cases, the IRB may grant an exemption from the required reporting. Please refer to Appendix A: Mandatory Reporting of AIDS and HIV Infection in Utah for additional details.

Points to Address

New Study Application:

1. **Section 4.2e, HIV antibody testing:** Please answer “Yes.”
2. **HIV Antibody Testing Checklist:** Complete this page entirely.

Protocol Summary:

1. **HIV Testing:** The process of informed consent to HIV antibody testing is especially sensitive. Subjects must be informed of the potential psychological, economic, legal, and medical significance of the test results prior to testing. The protocol must address how this issue will be handled. Please also indicate who by name and qualification will be available to provide HIV counseling.
2. **HIV Testing:** Please address the issues and implications involved in the communication of test results, and the implications or possible effects of communicating those results.

Consent Document:

1. **Study Procedures:** Please add that subjects will be offered HIV counseling before undergoing testing.
2. **Risks:** Please describe any potential psychological, economic, legal, and medical risks that may result from the HIV test results.
3. **Confidentiality:** Please add that a diagnosis of HIV or AIDS must be reported to the State Health Department (unless you have received an exemption from this reporting requirement, in this case please attach the exemption).
4. **Confidentiality:** Please add that test results will be communicated with appropriate counseling and partner notification services, by either the investigator or arrangements made by the investigator with the subject's regular health provider. Please specify how this will be done.
5. **Confidentiality:** Please state that test results will be stored in locked cabinets, accessible only to the investigator and other authorized people.
6. **Costs and Compensation:** Please add that the costs of HIV testing will be borne by the research study and will not be charged to the patient, insurance company or other third party payer.

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References & Links

Federal Domestic

HIV/AIDS information and resources <http://www.aids.gov/>

Utah Bureau of

Communicable Disease Control <http://health.utah.gov/cdc/sp.htm>

Utah Bureau of

Epidemiology: Disease Reporting <http://health.utah.gov/epi/report.html>

Utah Code 26-6-3.5:

Reporting AIDS and HIV Testing http://le.utah.gov/~code/TITLE26/htm/26_06_000305.htm

Utah Administrative

Code R388-803: HIV Test Reporting <http://www.rules.utah.gov/publicat/code/r388/r388-803.htm>

APPENDIX A: Mandatory Reporting of AIDS and HIV Infection in Utah

Because of the nature and consequences of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus infection (HIV), the reporting of those conditions is required in Utah (see Utah Code 26-6-3.5). Health care providers are required to report all positive results, presence of antibodies, and repeatedly reactive tests of AIDS or HIV infection to the Utah Department of Health or the local health department where the patient resides (see Utah Administrative Code R388-803). For details on how to report, please refer to the Utah Bureau of Epidemiology Disease Reporting website.

The IRB may grant an exemption from the required reporting. The exemption is permitted in research conducted by universities or hospitals under the authority of Institutional Review Boards if the study is funded in whole or in part by research grants; and if anonymity (anonymity means the patient's personal information would not be reported to the Department of Health) is required in order to obtain the research grant or to carry out the research. The exemption from reporting will only be granted if the following is submitted to the Utah Department of Health:

- A summary of the research protocol;
- A written approval of the Institutional Review Board;
- A letter showing funding sources and the justification for requiring anonymity; and
- A quarterly report indicating the number of HIV infected individuals enrolled in the study.

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