



REPORTABLE DISEASES

Description

Local and state health departments require certain diseases be reported in the interest of public health. These diseases are called “reportable diseases”. Cases of reportable diseases are required to be reported to local and state health departments by health care providers, hospitals or laboratories. By complying with reporting requirements, state and local health departments can improve public health through prevention services, treatment and care, and disease control. Each state has its own laws and regulations defining reportable diseases. The list of reportable diseases may vary over time.

Investigator Responsibilities

Investigators should be familiar with the local reporting requirements because reporting requirements will vary based on location. You may refer to Utah Department of Health website for a current list of Utah’s reportable diseases, including the reporting time frame and how to report.

IRB Requirements

If a reportable disease may be detected, diagnosed or treated during the course of a research study at the University of Utah, the IRB may request the following:

1. The informed consent document states the intent to test for the reportable disease.
2. The informed consent document states the investigator’s responsibility to report to the appropriate agency and how the reporting will affect confidentiality.
3. If a positive result and the notification to the appropriate health department may result in partner notification activities, this should be stated in the confidentiality section.
4. The informed consent document describes opportunities for follow-up counseling or medical care, as applicable.

The following text is an example of language in the consent document, “*As part of your participation in this study, we will test your blood for <<list reportable diseases>>. Positive results must be reported to you and the Utah Department of Health. If you do not want to be tested, you may choose not to participate in this research study. If you receive a positive test result, the Utah Department of Health or local health department may conduct partner notification activities and counseling if applicable.*”

Requests for Exemption of 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.

Investigators can find extensive provider resources in the event a research participant tests positive for HIV on the [Utah AIDS Education and Training Center \(UAETC\) Website](#).

In rare cases, 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

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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.

Points to Address

New Study Application:

1. **Resources and Responsibilities page (question 4):** If applicable, describe plans to refer participants for follow-up care or counseling.

Consent Document:

1. **Confidentiality:** Please state which reportable disease the participant will be tested for and that a positive result must be reported to the local or State Health Department where the participant resides. State that if a participant does not want to be tested, they can choose not to participate in the study.
2. **Confidentiality:** If a positive result and the subsequent notification to the appropriate health department may result in partner notification activities, please inform participants that the Utah Department of Health or local health department shall conduct partner notification activities and counseling as per their own policies.

References & Links

*Utah Department of Health
Bureau of Epidemiology:
Disease Reporting*

<http://health.utah.gov/epi/reporting/>

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