



REPORTABLE DISEASES MANDATORY REPORTING

Description

This guidance document outlines information that should be shared with participants during the informed consent process relating to the 1) disclosure of confidential information of reportable diseases; 2) disclosure of abusive situations; and 3) disclosure of information about harming others or themselves. In some cases, the disclosure of confidential information is mandatory (by law or University policy) and in other cases, the researcher may have a professional duty to make such disclosures. For the citations of applicable laws, please see the University of Utah Board Member Guidance Series: Applicable State Laws.

Reportable Diseases

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.

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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 \(rev. 7/2020\)](#) of Utah's reportable diseases, including the reporting time frame and how to report.

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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.

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Please see Appendix A of this document for more information regarding requests for exemption of mandatory reporting of AIDS and HIV infection in Utah.

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Abuse

In some cases, mandatory reporting of confidential information may be required. If researcher is legally obligated to reveal instances of child abuse, elder abuse, or abuse of the disabled, a disclosure should be given during the informed consent process. If your study involves the possibility of disclosure of abusive situations, mandatory language must be included in the consent document. See the Supplemental Elements tab on the Consent Document Checklist found on the IRB website.

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Sexual Misconduct and Discrimination

4- Under University of Utah policy, most University employees (including researchers) are required to report situations involving sexual misconduct and discrimination to the Office of Equal Opportunity and Affirmative Action (OEO/AA). This includes research activities that may result in a participant who is a University of Utah student disclosing alleged sexual violence. The PI/study team member to whom incidents of this alleged sexual violence is disclosed is considered a "mandatory reporter" and has an obligation to report these incidents to the University of Utah Office of Equal Opportunity, Affirmative Action, and Title IX (OEO). If the research is such that participants may divulge experiences with sexual violence and participants are adult students (18+) at the University of Utah, the consent document should include language that outlines this required reporting. See Supplemental Elements tab on the Consent Document Checklist found on the IRB website.

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Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



Threat to Self or OthersThe 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."

In some cases, a researcher may have a duty to disclose information necessary to prevent a serious and imminent threat to the health or safety of the patient or others. If a study involves the possibility that participants may disclose information about harming themselves or others, investigators should include a statement about the potential breach of confidentiality. Suggested language for the consent document can be found under the Supplemental Elements tab on the Consent Document Checklist found on the IRB website.

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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 R386-702-3). For details on how to report, please refer to the Utah Bureau of Epidemiology Disease Reporting website.

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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 Utah Department of Health may grant an exemption from the required reporting (see Utah Code 26-6-3.5(2)(b); Utah Administrative Code R386-702-3(9)). In the course of University of Utah IRB approval, the University of Utah IRB may indicate institutional support for an investigator's exemption application to the Utah Department of Health. 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. Researchers must apply to the Utah Department of Health for approval of a reporting exemption prior to beginning the study. When applying for an exemption from reporting, the following should be submitted to the Utah Department of Health:

- A summary of the research protocol;
 - A written approval of the University of Utah Institutional Review Board; and
 - A letter showing funding sources and the justification for requiring anonymity.
- Studies granted an exemption must provide the Department of Health with an annual report of the number of individuals informed of their HIV positive status and receiving extensive counseling, as well as a report of compliance with state mandated partner notification.

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Points to Address

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New Study Application:	<u>1.3-Resources and Responsibilities page (question 4)</u> : 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.

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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.

3. Confidentiality: If mandatory reporting is required of the investigator considering the scope of the research, ensure that the participants are informed of such potential disclosures.

References & Links

BMGS: Applicable State Laws <https://irb.utah.edu/guidelines/investigator.php>

University of Utah Consent Document Checklist – Supplemental Elements Tab <https://irb.utah.edu/informed-consent/consent-document-checklist.php>

University of Utah Office of Equal Opportunity (OEO/AA) <https://oeo.utah.edu/>

Utah Department of Health Bureau of Epidemiology: Disease Reporting <http://health.utah.gov/epi/reporting/>

Utah Department of Health Reportable Disease List (Rev. 7/2020~~11~~/2019) http://health.utah.gov/epi/reporting/Rpt_Disease_List.pdf

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Appendix A: Requests for Exemption of Mandatory Reporting of AIDS and HIV Infection in Utah

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