

APPLICABLE STATE LAWS

Description

The University of Utah IRB seeks assistance from the University’s Office of General Counsel when assessing the applicability and requirements of federal and state law. Additionally, the Office of General Counsel helps resolve conflicts between federal, state, and other applicable laws. Assistance is also available for investigators conducting research under the jurisdiction of the IRB. The Office of General Counsel may be contacted by telephone at (801) 585-7002.

For research that is conducted outside of the United States, the IRB and the Office of General Counsel works with the investigators and local authorities to determine the laws applicable to the research. The IRB may also consult with the Office of Human Research Protections International Activities program (<http://www.hhs.gov/ohrp/international/index.html>).

All investigators conducting research must follow federal, state, and other applicable laws. IRB members are responsible to apply state laws, when applicable to the research under review, and determine that research is conducted in accordance with these laws. Utah State laws commonly implicated by research activities are listed below.

Law	Summary	Applicability	Related Documents
Consent for Medical Treatment			
Advance Health Care Directive Act [Utah Code 75-2a-101 et. seq.]	Utah recognizes special power of attorney documents and medical directives in which individuals can provide advance directives of medical care in the event the individual is not able to make his or her wishes known. Through power of attorney documents, an individual can also name another individual who can consent on his or her behalf. <u>Utah also provides a list of default surrogates. A default surrogate is an individual who may make health care decisions for the patient who lacks health care decision-making capacity, when a challenge of that determination is not upheld by the court and when the appointed agent or court appointed guardian is absent or not reasonably available. The surrogate must be 18 years of age or older, have health care decision-making capacity, be reasonably available and not disqualified by the individual patient.¹</u>	<u>Investigators must provide a list of individuals in descending order of priority who may be sought as a legally authorized representative (LAR).</u> <u>The JRB must approve the list of individuals who may be eligible to serve as a potential LAR.</u> If <u>investigators</u> must obtain consent from an <u>LAR</u> <u>legally authorized representative</u> , the investigator must <u>document</u> <u>establish</u> that the consenting individual has the legal authority to do so.	Investigator Guidance Series: <u>(Research Involving Individuals with Decisional Impairment)</u> <u>Surrogate Consent by a Legally Authorized Representative</u> <u>Board Member Guidance Series: Ethical Considerations for Surrogate Consent</u> Signature Block Samples

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<p>Consent of Minor to Treatment for Pregnancy and Childbirth [Utah Code 78B-3-406]</p>	<p>Any female, regardless of age, has authority to consent to health care for treatment of her pregnancy or childbirth. This does not extend to health care decisions regarding abortion.</p>	<p>In Utah, a person under the age of 18 is no longer considered a child as defined by federal regulations and Subpart D does not apply if she is receiving care or treatment for a pregnancy or childbirth (provided that the research is directly connected to the condition). This does not extend to health care decisions regarding abortion.</p>	<p>Investigator Guidance Series: Research Involving Children</p>
<p>Consent of a Minor to Treatment for Sexually Transmitted Disease [Utah Code 26-6-18]</p>	<p>A minor, regardless of his or her age, is authorized under Utah law to consent to medical care for diagnosis or treatment for a sexually transmitted disease. This holds true even if the results of the test are ultimately negative.</p>	<p>In Utah, a person under the age of 18 is no longer considered a child as defined by federal regulations and Subpart D does not apply if he/she is receiving care or treatment for a sexually transmitted disease (provided that the research is directly connected to the condition).</p>	<p>Investigator Guidance Series: Research Involving Children</p>
<p>Consent to Health Care [Utah Code 78B-3-406(6)]</p>	<p>Lists the persons who are authorized and empowered to consent for any health care not prohibited by law.</p>	<p><u>Investigators must provide a list of individuals in descending order of priority who may be sought as a legally authorized representative (LAR).</u></p> <p><u>The IRB must approve the list of individuals who may be eligible to serve as a potential LAR.</u></p> <p>If Investigators must obtain consent from a legally authorized representative (including permission of a parent/guardian), the investigator must establish document that the consenting individual has the legal authority to do so.</p>	<p>Investigator Guidance Series (Parental Permission; Research Involving Individuals with Decisional Impairment)</p> <p><u>Surrogate Consent by a Legally Authorized Representative)</u></p> <p><u>Board Member Guidance Series: Ethical Considerations for Surrogate Consent</u></p> <p>Signature Block Samples</p>
<p>Emancipation [Utah Code 80-7-105 and State of Utah v. C.R. and R.R., 797 P.2d 459, 464 (Utah App. 1990)]</p>	<p>A person 16-years of age or older may petition the court to obtain the legal status of emancipation. An emancipated minor may obtain health care without parental consent.</p> <p>The common law doctrine of emancipation is accepted unless it conflicts with the statutes or constitutions of the United States or of Utah.</p>	<p>If an individual under the age of 18 is emancipated, he or she is not considered a child as defined by federal regulations, in which case Subpart D does not apply. Investigators should contact the Office of General Counsel for guidance regarding emancipated youth.</p>	<p>Investigator Guidance Series: Research Involving Children</p>

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Governmental Immunity			
Governmental Immunity [Utah Code 63G-7-101 et. seq.]	The University of Utah is a governmental entity and part of the Utah State government. If a participant is injured in a study, and wants to sue the University or the doctors, nurses, students, or other people who work for the University, special laws apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government and limits the amount of money a person may recover.	Investigators must include a liability statement in the consent document which explains the limits of a claim against the University of Utah. Board Members verify the required liability language is included in the consent document.	Consent Document Checklist (Supplemental Elements) Reviewer Checklist: Consent
Immunity of Governmental Employees and Volunteers from Suit [Utah Code 63G-7-102 and 63G-7-201]	Employees of a governmental entity, and individuals acting in a volunteer capacity for the governmental entity, are immune from suit for any injury that results from the exercise of a governmental function. The University of Utah will defend and indemnify University employees and volunteers who are named in a lawsuit that is based on the person's service to the University unless the employee or volunteer was acting outside of the course and scope of his or her employment/volunteer activity, was acting under the influence of drugs or alcohol, commits fraud, or acts with actual malice or willful misconduct.	Board Members who are not employees of the University of Utah are considered to be acting in a volunteer capacity for the University of Utah.	N/A
Waivers of Immunity - Exceptions [Utah Code 63G-7-301]	The University itself can be sued if a plaintiff establishes that the injury was proximately caused by a negligent act or omission of an employee committed within the scope of employment.	N/A	N/A

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Miscellaneous			
Abortion, Pathologist's Report [Utah Code 76-7-309]	Any human tissue removed during an abortion shall be submitted to a pathologist who shall make a report, including, but not limited to whether the pregnancy was aborted by evacuating the uterus, and whether a medical record indicates that, through a prenatal screening or other diagnostic test, the aborted fetus had or may have had Down syndrome.	Investigators must confirm that prior to any use for research, tissues are submitted to a pathologist as per state law.	N/A
Utah Public Officers' and Employees' Ethics Act [Utah Code 67-16-1 et seq.]	University of Utah employees are prohibited from soliciting or accepting a gift that is intended to, or could improperly influence a public employee in the performance of his or her public duties. Occasional non-monetary gifts with a value of not more than \$50 are generally excluded from the Act. Employees who violate the Act are subject to termination and criminal penalties. The University Conflicts of Interest Officer and the Office of General Counsel can provide more information on this statute.	Conflicts of interest must be declared and resolved. Investigators must complete Conflict of Interest disclosures. Board members must declare conflicts of interest and may not participate in the review or approval of studies when a conflict exists.	IRB SOP 801 (Conflicts of Interest) COI Disclosure form IRB SOP 304 (IRB Convened Meeting Administration) IRB Member Recusal Agreement

Privacy			
Genetic Testing Privacy Act [Utah Code 26-45-101 et. seq.]	Utah's Genetic Testing Privacy Act places restrictions on the use/disclosure of private genetic information to employers and to health insurers.	Investigators should consider the protections provided by law regarding the disclosure of genetic information when writing the risks and confidentiality sections of the informed consent document. Board Members review the consent document to ensure the genetic guidelines are met.	Investigator Guidance Series: Genetic Research Reviewer Checklist: Consent

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Reporting			
<p>Mandatory Disease Reporting [Utah Code 26-6-6, 26-23b-103; Utah Administrative Code R386-702-3, -4, -6]</p>	<p>Health care providers are required to report communicable diseases no later than 24 hours after a suspected diagnosis or within three working days of identification, depending on the disease (refer to https://epi.health.utah.gov/ for a current list of Utah's reportable diseases and required reporting timeframe). Health care providers who use electronic reporting to the Department of Health must report all final laboratory results within 24 hours.</p>	<p>If testing is performed for any communicable or infectious diseases reportable by state law as a result of study participation, Investigators disclose mandatory reporting in the consent document.</p> <p>Board Members verify disclosure of mandatory reporting that is made in the consent document.</p>	<p>Investigator Guidance Series: Reportable Diseases</p> <p>Consent Document Checklist (Supplemental Elements)</p> <p>Reviewer Checklist: Consent</p>
<p>Mandatory Reporting of Abuse of Vulnerable Adult [Utah Code 62A-3-305]</p>	<p>Any person who has reason to believe that any vulnerable adult has been the subject of abuse, neglect, or exploitation shall immediately notify Adult Protective Services intake or the nearest law enforcement agency.</p>	<p>If an Investigator has reason to believe a vulnerable adult has been abused, neglected or exploited, he/she must report such observations as described.</p> <p>Since it is not possible to predict the observation of abuse or neglect, if a study involves the <i>possibility</i> of the disclosure of abusive situations, Investigators should include language regarding the reporting of abuse in the consent document.</p> <p>Board Members verify language regarding the reporting of abuse is in the consent document, if applicable.</p>	<p>Consent Document Checklist (Supplemental Elements)</p> <p>Reviewer Checklist: Consent</p>
<p>Mandatory Reporting of Cancer [Utah Administrative Code R384-100, Utah Code 26-23-6]</p>	<p>All hospitals, radiation therapy centers, and other facilities and health care providers are required to report to the Utah Cancer Registry new cases of cancer and noncancerous brain tumors within six months of diagnosis. Penalties for non-compliance are described in the Utah Code.</p>	<p>If an Investigator is a health care provider who diagnoses cancer in a patient, he/she is responsible for the mandatory reporting of cancer as described.</p>	<p>N/A</p>

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<p>Mandatory Reporting of Child Abuse [Utah Code 62A-4a-403]</p>	<p>Any person that has reason to believe that a child has been subjected to abuse, or neglect, or who observes a child being subjected to conditions or circumstances which would reasonably result in sexual abuse, physical abuse, or neglect, shall immediately notify the nearest law enforcement agency, or office of the Division of Child and Family Services.</p>	<p>If an Investigator has reason to believe a child has been abused, neglected or observes a child being subjected to conditions which would reasonably result in abuse or neglect, he/she must report such observations as described.</p> <p>Since it is not possible to predict the observation of abuse or neglect, if a study involves the <i>possibility</i> of the disclosure of abusive situations, Investigators should include language regarding the reporting of abuse in the consent document.</p> <p>Board Members verify language regarding the reporting of abuse is in the consent document, if applicable.</p>	<p>Consent Document Checklist (Supplemental Elements)</p> <p>Reviewer Checklist: Consent</p>
<p>Mandatory Reporting of Injury as a Result of Criminal Conduct [Utah Code 26-23a-2]</p>	<p>Any health care provider who cares for any person who suffers from an injury (including a self-inflicted injury) resulting from criminal conduct (including gunshot wounds, stabbings, explosive devices), shall immediately report to a law enforcement agency the facts regarding the injury.</p>	<p>It is not possible to predict when a health care provider will care for a person who suffers from an injury resulting from criminal conduct. If an Investigator is a health care provider, he/she is subject to mandatory reporting of injury as a result of criminal conduct as described.</p>	<p>N/A</p>
<p>Mental Health Reporting [Utah Code 78B-3-502]</p>	<p>A therapist has a duty to warn or take precautions when a client or patient communicates to the therapist an actual threat of physical harm against a reasonably identifiable victim. The therapist should notify a law enforcement officer or agency of the threat and make reasonable efforts to communicate the threat to the victim. Therapists are required to report child abuse or neglect, and abuse or neglect of vulnerable adults, as outlined above.</p>	<p>If a study involves the <i>possibility</i> that participants may disclose information about harming others, Investigators should include a statement about the potential breach of confidentiality.</p>	<p>Consent Document Checklist (Supplemental Elements)</p>

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<p>Reporting AIDS and HIV Testing [Utah Code 26-6-3.5; Utah Administrative Code R386-702</p>	<p>Health care providers must report AIDS or HIV infection to the Utah Department of Health or a local health department.</p> <p>Provides reporting requirements and details of Department of Health authority to grant exemption from reporting requirement for certain research conducted at universities and hospitals.</p>	<p>Investigators complete the HIV Testing Checklist and disclose mandatory reporting in the consent document.</p> <p>Board Members verify that disclosure of mandatory reporting is made in the consent document. In rare cases, Board Members may support an investigator's application to the Department of Health for exemption from reporting requirements consistent with state law.</p>	<p>Investigator Guidance Series: Reportable Diseases</p> <p>Consent Document Checklist (Supplemental Elements)</p> <p>Reviewer Checklist: Consent</p>
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ⁱ In descending order of priority the following individuals, if willing and able, may act as default surrogate health care decision maker: 1) Spouse (unless legally separated or divorced from the individual or a court finds that the spouse has acted in a manner that should preclude the spouse from having a priority position as a default surrogate); 2) Child; 3) Parent; 4) Sibling; 5) Grandparent; 6) Grandchild; or if no qualified family member is willing or able to serve as surrogate health care decision maker, a person other than those listed above can serve if that person has health care decision-making capacity, has exhibited special care and concern for the patient, is familiar with the patient's personal values and is reasonably available to act as a surrogate. If there is disagreement among multiple members of a given class (i.e., 2 through 6 above) of potential surrogates, the health care provider will comply with the decision of the majority in that class. The patient, even if the patient lacks healthcare decision-making capacity, can, by law, disqualify any default surrogate.

ⁱⁱ The following persons are authorized and empowered to consent to any health care not prohibited by law: any parent, whether an adult or a minor for his/her minor child; any married person, for his or her spouse who is unable to consent due to the patient's physical or mental condition; any person temporarily standing in loco parentis, whether formally serving or not, for the minor under his or her care and any guardian for his or her ward; any person 18 years of age or over for his or her parent who is unable to consent due to the patient's physical or mental condition; any patient 18 years of age or over; any female regardless of age or marital status, when given in connection with her pregnancy or childbirth; in the absence of a parent, any adult for his or her minor brother or sister; in the absence of a parent, any grandparent for his or her minor grandchild; an emancipated minor; a minor who is legally married; unaccompanied homeless minor who is 15 years or older.

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