

Institutional Profile & Local Context Information

On this page you will find the Institutional Profile and Local Context information for the University of Utah and our local community in the State of Utah. If you need more information or need assistance completing questions from a single IRB (SIRB), please get in touch with your IRB SIRB Reliance team contact, or email uuirbreliance@utah.edu.

Section 1: Institutional Profile	
Institution Name	University of Utah
Federalwide Assurance (FWA)	FWA00003745 Expiration: 11/16/2025 Does the FWA extend to non-federally funded research? No
AAHRPP Accreditation	Yes
Institutional Official	Erin Rothwell, PhD Vice President for Research (Interim) 201 S Presidents Circle, Room 201 Salt Lake City, UT 84112 801-581-7236 erin.rothwell@utah.edu www.research.utah.edu
Primary IRB of Record	University of Utah IRB 75 S 2000 E Salt Lake City, UT 84112 Phone: 801-581-3655 Fax: 801-587-9138 irb@hsc.utah.edu www.irb.utah.edu
Primary HRPP/IRB Contacts	Ann Johnson, PhD IRB Director 801-581-3655 ann.johnson@hsc.utah.edu
Does your site have a quality assurance (QA)/audit group responsible for overseeing ongoing research?	Yes
Are there any investigations, audits, or findings (e.g. OHRP, FDA, or local audits) over the past 3 years that would be relevant to the conduct of human subjects' research at your site?	No Information about our inspection history can be found at: https://irb.utah.edu/about/irb-fwa.php
Is your site a covered entity under HIPAA?	Hybrid The University of Utah includes academic departments that are outside the Covered

	Entity, and medical departments, clinics, and hospitals that are inside the Covered Entity.
What human subjects' protection training course(s) are completed by researchers at your site?	CITI, GCP

Section 2: Local Context

What state and local laws and/or local requirements should be considered when ceding oversight to an external IRB?	<p>The guidance document titled Applicable State Laws outlines all applicable state laws that must be followed. This includes, but is not limited to, age of majority, consent for health care in minors, mandatory health reporting, consent using a legally authorized representative, use of generative AI, and using social media platforms with minors.</p> <p>Click here and go to Applicable State Laws.</p>
Age of Majority in Utah	18
How does a minor become emancipated in Utah?	<ul style="list-style-type: none"> a) By judicial petition b) By marriage c) By joining the armed forces
What circumstances affect age of consent in Utah?	<p>The guidance document titled Research Involving Children describes: "In certain circumstances Utah law authorizes an individual under the age of 18 to function as an adult when seeking or receiving health care. In such circumstances, parental permission is not required as part of the research consent process. When an individual under the age of 18 is authorized to consent for care or treatment because the care or treatment is connected to a sexually transmitted disease or pregnancy/childbirth, the individual may only consent for himself/herself in connection with that treatment or care and the individual may only provide full informed consent for research that is directly connected to that treatment or care. Researchers are required to conduct a full consent process in a way that is understandable to the individual under 18. The IRB may require parental permission or other methods to ensure comprehension of the study prior to enrollment."</p> <p>Click here and go to Research Involving Children.</p>
Does your site require the use of a HIPAA waiver to review medical records solely for the purpose of identifying potential research participants?	Yes

<p>Are there any state or local laws or institutional policies that require record keeping for longer than federal law requires under the Privacy Rule, the Common Rule, FDA regulation, or other applicable research regulation?</p>	<p>No</p>
<p>Are there any diseases that require mandatory reporting to health authorities in Utah?</p>	<p>Yes, all communicable diseases.</p>
<p>What are the circumstances that affect consent for cognitively or decisionally impaired adults?</p>	<p>The guidance document Research Involving Individuals with Decisional Impairment outlines Utah state law as follows: “Utah provides a list of individuals who are authorized to consent to medical treatment for another when the patient is unable to consent on his or her own behalf. The statute provides that the consent must not be otherwise prohibited by law. The statute provides that the following individuals may consent on behalf of another. These individuals will be considered to meet the DHHS and FDA definition of a legally authorized representative for research purposes and is an acceptable legally authorized representative in accordance with VA policy:</p> <ul style="list-style-type: none"> a) Any married person, for a spouse b) Any person 18 years of age or older for his or her parent who is unable by reason of age, physical or mental condition, to provide such consent c) Any individual designated with power of attorney d) A legally appointed guardian <p>Click here and go to Research Involving Individuals with Decisional Impairment.</p>

Section 3: Institutional Informed Consent and Authorization Requirements

For template language to help you prepare your consent documents for use in Utah, please review our [consent document guide](#).

<p>Research-Related Injury Language</p>	<p>The University of Utah has specific language that must be included regarding research-related injury.</p>
<p>HIPAA Language</p>	<p>The University of Utah prefers to use compound Authorization, i.e., that the HIPAA language be included in the Consent Document, not as a separate document. The University of Utah has specific language that must be included for HIPAA Authorization.</p>
<p>Person to Contact Language</p>	<p>Local contact information for the PI and/or study team must be included in addition to any other contact information provided for the study as a whole.</p>



Data or Biospecimen Banking Language	The University of Utah requires that several components describing banking be included when a study proposes saving data or biospecimens for potential future research.
Incidental Genetics Findings Language	The University of Utah requires language addressing the potential for identification and disclosure of incidental genetic findings.
Legally Authorized Representative (LAR) Signature Block	<p>The University of Utah requires that the following LAR designations be included with the LAR signature block:</p> <p><input type="checkbox"/> Individual authorized with legal authority to provide consent on behalf of the participant (e.g. an individual named in an Advanced Health Care Directive or in a Medical Power of Attorney)</p> <p><input type="checkbox"/> Spouse</p> <p><input type="checkbox"/> Adult child (18 years of age or over) for his or her parent</p> <p>Please consult our guidance titled “Surrogate Consent” for more information. Utah has several requirements related to legally authorized representatives.</p>
Certificates of Confidentiality (CoC)	The University of Utah prefers that the consent document remain silent on the Certificate protections.
Short Form Consent and Non-English Speaking Participants	<p>Yes, our site allows a short form consent process for individuals with limited English proficiency.</p> <p>Local policy requires all prospective research with participant interaction conducted by University of Utah researchers within the state of Utah, to have provisions for including people who speak Spanish. Learn more at: https://irb.utah.edu/blog/posts/2023/march/spanish.php.</p> <p>Studies may utilize either a full Spanish translation of the consent document or the Spanish Short Form consent process, depending on what is most reasonable for the study. Provisions must include the following:</p> <ul style="list-style-type: none">• Recruitment methods for people who speak Spanish, including translated recruitment materials and interpretation services if individuals would like to discuss the study.• Consent processes for people who speak Spanish, including translated consent documents and interpretation services during the consent process and discussion.• Methods for ongoing communication with and data collection from participants who speak Spanish, including translated study materials and interpretation services for ongoing communication.

Section 4: Local Ancillary Reviews	
Are any ancillary reviews required at your site?	Yes Our Human Research Protection Program (HRPP) includes several different components.
Conflict of Interest Review	Required for all research conducted at the University of Utah. Review conducted by the University of Utah Conflict of Interest Committee. Management plans required by the Committee will be communicated to the internal or external IRB of record via ERICA and/or the University of Utah HRPP Review Process.
Scientific and Facilities Reviews	The following groups/committees require review when a study involves any component relevant to their jurisdiction: <ul style="list-style-type: none"> a) Center for Clinical Translational Services b) Huntsman Cancer Institute Project Review & Monitoring Committee c) Institutional Biosafety Committee d) Primary Children’s Hospital e) Radiological Drug Research Committee and Human Use Subcommittee f) Resource for Genetic and Epidemiological Research Requirements and results determined required by the group/committee will be communicated to the internal or external IRB of record via ERICA and/or the University of Utah Facilitated Review Process.

Section 5: Local HRPP Review

The University of Utah may choose to rely on an external IRB. In this case, the UU IRB review is deferred to another IRB, such as a Single IRB (SIRB). Though IRB review may be conducted by an external IRB, the University of Utah uses a Human Research Protection Program (HRPP) review process to ensure that Utah State laws and University of Utah-specific requirements are met. The HRPP review process is conducted by the UU IRB.

University of Utah investigators must follow this HRPP review process to initiate a study at the University of Utah. **Research may not begin at our site** until the study team receives formal notification from the HRPP that our site has been activated by the HRPP.

Section 6: Characteristics of the Local Community

Nine out of every 10 Utahns live in an urban area, but Utah’s urban areas only represent 1.1% of the state’s land area. Utah’s urban and rural residents share similar income levels, household types, and educational levels, but vary in age and racial and ethnic makeup. Utah’s demographic

profile features a youthful, aging, and predominantly urban state that is becoming more racially and ethnically diverse.

The University of Utah main campus and health sciences center is located in Salt Lake County, which is the most densely populated area of the state (just over one million people), with a total state population of over three million people. Utah is estimated to be predominantly white/Caucasian, with nearly one in four (24%) Utahns identifying as a racial or ethnic minority.

Utah's population is aging due to declining fertility rates and the aging of the adult population. National surveys estimate that between 12% and 25% of adults in Utah have a disability.

Utah includes the largest population of self-identifying religious adherents of any state – estimated at 76.1% of the population, compared to 48.6% for the nation. Roughly half of the state's population identify as members of the Church of Jesus Christ of Latter-Day Saints. Utah also includes a large multi-lingual refugee population, and is predominantly politically conservative, with increasing areas of liberal and progressive communities in more populated areas of the state. 1 in 7 Utahns older than age 5 speaks a language other than English in their home, with the top five languages spoken in the state being English (85%), Spanish (~10%), Chinese, German, and Navajo (sources: [Utah Department of Health and the Gardener Policy Institute of Utah](#)).

Utah includes a highly educated population, with an estimated 45% of adults having at least some college education. Utahns are generally supportive of quality human subject research. The state is a center of education, information technology and research, agriculture, mining, ranching, salt production, and is a major tourist destination for outdoor recreation.