



# INSTITUTIONAL REVIEW BOARD

THE UNIVERSITY OF UTAH

## Institutional Profile and Local Context

Section 1: General HRPP Information	
Institution Name	University of Utah
Federalwide Assurance (FWA)	FWA00003745
AAHRPP Accreditation	Yes
Institutional Official	<b>Erin Rothwell, PhD</b> Interim Vice President for Research Professor, Obstetrics and Gynecology 10 S 2000 E Annette Poulson Cumming Bldg. Salt Lake City, UT 84112 801-581-5407 <a href="mailto:erin.rothwell@utah.edu">erin.rothwell@utah.edu</a> <a href="http://www.research.utah.edu">www.research.utah.edu</a>
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 <a href="mailto:irb@hsc.utah.edu">irb@hsc.utah.edu</a> <a href="http://www.irb.utah.edu">www.irb.utah.edu</a>
Primary HRPP/IRB Contacts	Ann Johnson, PhD IRB Director 801-213-7156 <a href="mailto:ann.johnson@hsc.utah.edu">ann.johnson@hsc.utah.edu</a>

Section 2: Local Context	
What state and local laws and/or local requirements should be considered when ceding oversight to an external IRB?	The guidance document titled <b>Applicable State Laws</b> 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, and consent using a legally authorized representative.  <a href="#">Click here</a> and go to <b>Applicable State Laws</b> .
Age of Majority in Utah	18
How does a minor become emancipated in Utah?	a) By judicial petition b) By marriage c) By joining the armed forces
What circumstances affect age of consent in Utah?	The guidance document titled <b>Research Involving Children</b> 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



# INSTITUTIONAL REVIEW BOARD

THE UNIVERSITY OF UTAH

	<p>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><a href="#">Click here</a> and go to <b>Research Involving Children.</b></p>
<b>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?</b>	No
<b>Are there any diseases that require mandatory reporting to health authorities in Utah?</b>	Yes: all communicable diseases.
<b>What are the circumstances that affect consent for cognitively or decisionally impaired adults?</b>	<p>The guidance document <b>Research Involving Individuals with Decisional Impairment</b> 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"><li>a) Any married person, for a spouse</li><li>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</li><li>c) Any individual designated with power of attorney</li><li>d) A legally appointed guardian</li></ul> <p><a href="#">Click here</a> and go to <b>Research Involving Individuals with Decisional Impairment.</b></p>
<b>Section 3: Institutional Informed Consent and Authorization Requirements</b>	
<b>Research-Related Injury Language</b>	The University of Utah has specific language that must be included regarding research-related injury.



# INSTITUTIONAL REVIEW BOARD

THE UNIVERSITY OF UTAH

	<p><a href="#">Click here</a> and go to <b>Consent and Authorization Template</b>, and see the Research Related-Injury section.</p>
<b>HIPAA Language</b>	<p>The University requires 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><a href="#">Click here</a> and go to <b>Consent and Authorization Template</b>, and see the Authorization For Use of Your Protected Health Information section.</p>
<b>Person to Contact Language</b>	<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>
<b>Tissue Banking Language</b>	<p>The University of Utah requires that several components describing tissue banking be included when a study proposes saving tissue for potential future research.</p> <p><a href="#">Click here</a> and go to <b>Tissue/Specimen Banking Consent Language</b>.</p>
<b>Incidental Genetics Findings Language</b>	<p>The University of Utah requires language addressing the potential for identification and disclosure of incidental genetic findings.</p> <p><a href="#">Click here</a> and go to <b>Consent and Authorization Template</b>, and see the New Information section.</p>
<b>Legally Authorized Representative (LAR) Signature Block</b>	<p>The University of Utah requires that the following LAR designations be included with the LAR signature block:</p> <ul style="list-style-type: none"><li><input type="checkbox"/> Spouse</li><li><input type="checkbox"/> Adult (18 years of age or over) for his or her parent</li><li><input type="checkbox"/> Individual with power of attorney</li><li><input type="checkbox"/> Guardian appointed to make medical decisions for individuals who are incapacitated</li></ul>
<b>Certificates of Confidentiality (CoC)</b>	<p>The University of Utah prefers that the consent document remain silent on the Certificate protections.</p>
<b>Section 4: Local Ancillary Reviews</b>	
<b>Conflict of Interest Review</b>	<p>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 Facilitated Review Process.</p>
<b>Scientific and Facilities Reviews</b>	<p>The following groups/committees require review when a study involves any component relevant to their jurisdiction:</p> <ul style="list-style-type: none"><li>a) Center for Clinical Translational Services</li></ul>



- 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 Facilitated Review

The University of Utah may choose to rely on an external IRB. In this case, the UIIRB review is deferred to another IRB, such as a Central IRB (CIRB). Though IRB review may be conducted by an external IRB, the University of Utah uses a facilitated review process to ensure that Utah State laws and University of Utah-specific requirements are met. The facilitated review process is conducted by the UIIRB.

University of Utah investigators must follow this facilitated review process in order to initiate a study at the University of Utah.

[Click here](#) and go to **Facilitated Review Process for the University of Utah**.

## Section 6: Characteristics of the Local Community

Utah includes rural, suburban, and urban communities. 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 85% white/Caucasian.

Utah includes a very religious community, with roughly half of the state's population identifying 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 (source: [Utah Department of Health](#)).

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.