

# Informed Consent Training Series: Informed Consent: Building from Basics



UtahStateUniversity

October 22, 2025  
*Nicole Vouvalis, Executive Director of Human  
Research Protections*

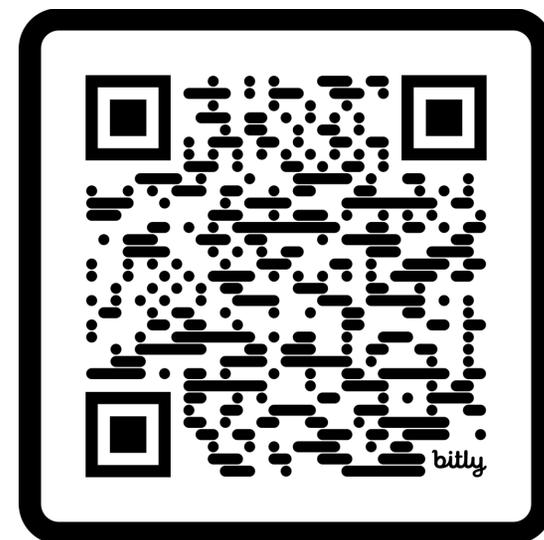
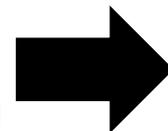
# Welcome & Housekeeping

**Welcome to the USU Institutional Review Board Fall 2025 Training Series!**

**This training is our first** in a series of monthly trainings spanning the Fall 2025 semester, including upcoming trainings on informed consent waivers and alterations, and models for exceptional informed consent processes.

**Let us know what training topics you want to see addressed in Spring 2026!**

**<https://research.usu.edu/irb/feedback> or scan**



# **Welcome & Housekeeping**



**To ask a question, use the Q&A function at the bottom of this webinar screen. Anonymous questions are permitted.**



**All sessions will be recorded, and the recordings and/or slides from the presentation will be posted to the IRB's website, which can be accessed at [irb.usu.edu](http://irb.usu.edu).**

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# The Institutional Review Board



# The Human Research Protection Program

## VP for Research

Responsible for overseeing all aspects of USU's Human Subjects Research portfolio & ensuring appropriate access to resources for a well-functioning Human Research Protection Program (HRPP)



### Human Research Protections Office

Manages the day-to-day aspects of implementing and overseeing the HRPP, including:

- Researcher training
- Coordination with COI, IBC, ICOI, SPO processes
- Receiving complaints, concerns, and questions from research participants

### The IRB

Reviews all proposed human subjects research at Utah State University according to:

- Established ethical standards,
- Policies & procedures, and
- Best practices

### Researchers

Responsible for carrying out and overseeing research with human participants in a manner that:

- Complies with the terms of IRB's review,
- Ensures adequate resources and training for the safe conduct of the research, and
- Takes proactive steps to ensure the health, safety, and well-being of research participants

# Utah State University IRB Review Standards

**Utah State University's Institutional Review Board conducts its reviews according to two prevailing ethical and regulatory standards:**

## **The Belmont Report**

- Respect for Persons
- Justice
- Beneficence

## **45 C.F.R. 46 (The Common Rule)**

- Subpart A: General Review standards
- Subparts C, D: Vulnerable Population Requirements

# Belmont Report

- Commission charged with identifying critical research-related principles in 1974
- The *Belmont Report* was produced in 1976
- Membership included 11 appointed individuals: scientists, physicians, lawyers, and one civil rights activist



# Belmont Standards: Respect for Persons

**Respect for Persons is the primary driver behind informed consent requirements. Using Belmont standards as a benchmark, to respect a person is to give appropriate weight to the person's opinions and choices.**

- In seeking informed consent from prospective research participants, we demonstrate respect by ensuring that those people have the information they need to make an informed decision about participation.
- When appropriate, researchers and their institutions sometimes demonstrate respect by providing extensive protection – this accounts for the informational advantage that researchers and institutions hold disproportionately, and also for scenarios where an individual might not be fully capable of self-determination.



UNITED STATES

Department of  
Health and Human  
Services

## The Common Rule

- The *Common Rule* came much later: in 1991, as a formal implementation of the Belmont Principles.
- Enshrined in 45 Code of Federal Regulations Section 46 (45 C.F.R. 46)

# **Common Rule Standards: Informed Consent**

**Two General Structures for Informed Consent in the Common Rule**

- 1. The Informed Consent Process**
- 2. The Informed Consent Documentation**

# USU IRB Informed Consent Standards

Belmont Principles

+

Common Rule Requirements

+

Accreditation Requirements

+

State, Federal, Sovereign, International, and/or  
Context-Specific Requirements



# Context-Specific Requirements

HIPAA

FERPA

General Data Protection Regulation (EU)

Personal Information Protection Law (China)

Protection of Pupil Rights Amendment (U.S.)

Electronic Signatures in Global and National Commerce Act (U.S.)

Health Information Technology for Economic and Clinical Health Act (U.S.)

Children's Online Privacy Protection Act (U.S.)

Utah Minor Protection in Social Media Act (Utah – currently stayed)



# Informed Consent

The communication process during which an individual is given important information about a procedure or treatment, and that interaction results in agreement or disagreement by that individual to undergo the procedure or treatment based on knowledge of relevant facts.

In most cases, for informed consent to be legally effective, it must also be documented.



# Informed Consent

Baseline Informed Consent process under the Common Rule:

1. Prospective participant is given complete relevant information about the study;
2. Prospective participant makes a decision whether to enroll after having an opportunity to consult with others (including members of the research team regarding questions they might have or loved ones regarding whether this is a good option for them); and
3. Prospective participant signs and prints their name, and the date, on a document, an executed copy of which is returned to them for their own records.



# Informed Consent Prohibitions

## Undue Influence

Influence by which a person is induced to act otherwise than by their own free will without adequate attention to the consequences.

## Coercion

The practice of persuading someone to do something by use of force or threats

### Examples:

- Compensation that is so great relative to the procedures that research participants do not consider the procedures
- Someone in a position of power asking a prospective participant to agree to the research
- Informing a participant that they cannot access needed medical care unless they participate in research



# Informed Consent – Required Elements

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- Key information about a federally funded study or clinical trial
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights,
- Identification of whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary,
- A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled,
- A statement that the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

# Informed Consent – Additional Elements

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study
- A statement that the subject's biospecimens or information may be used for commercial profit and whether the subject will or will not share in this commercial profit
- Whether the research will involve whole genome sequencing

# Informed Consent – Additional Requirements for IRB Review Process

“An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of the informed consent process is in accordance with Section 46 CFR 46.116. The IRB may require that information, in addition to that specifically mentioned in Section 116, be given to the subjects when in the IRB’s judgment the information would meaningfully add to the protection of rights and welfare of subjects.” 45 C.F.R. 46.109 – IRB Review Requirements

## Examples:

- Confidentiality disclosures
- Payment or compensation information
- Use of information protected by other legal structures
- COI Disclosures
- Formatting or images for enhanced comprehension

# Informed Consent – Summary of the Defined Standards

The informed consent standards that come from the Belmont Report and 45 CFR 46 can be summarized by thinking about a few important, salient concepts:

- Complete Disclosure
- Comprehensibility
- Voluntary
- Appropriate Audience
- Documentation

# Appropriate Audience

There are two populations commonly utilized at USU who require special attention to *who is being asked for informed consent*.

## Children

Child Assent  
+  
Parental Permission  
=  
Informed Consent

## Adults with Cognitive Impairments

Impaired Adult's Assent  
+  
Legally Authorized Representative  
=  
Informed Consent



## Resources

- [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research](#)
- A [video about](#) the Belmont Report
- USU IRB Informed Consent Templates: [Informed Consent Documents](#)
- OHRP Participant-Centered Informed Consent [Training](#)
- Request a Consultation – [Submission Form](#)
- Ask The IRB Slack – [Invite Link](#)



# Thank You!

Please use the feedback link on our home page (or scan this QR code) to request topics for Spring 2026 IRB trainings.

Upcoming Informed Consent Training Series Sessions:

- November 19, 11:00 a.m. to 12:00 p.m.: *Informed Consent Alterations & Waivers*

