GOALS FOR THIS PRESENTATION

- Cover a wide range of questions we’ve received this year from board members
- Help direct you to resources available online
- Remind you of important policies and procedures

Let’s chat!
IRB SOPs AND GUIDANCE
What is a “Short Form Translation” and how is it used?
“If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation.

“Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective.

“If investigators enroll subjects without an IRB approved written translation, a ‘short form’ written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally.”

-“A Guide to Informed Consent”, FDA.gov
**SHORT FORM CONSENT TRANSLATIONS**

**Q:** When should the short form be used?

**A:** We allow the short form in limited circumstances when a full translation is not practical, such as when funding is too limited (e.g. non-profit or cooperative group studies), or when a large number of non-English speaking participants is not anticipated.

**Q:** What will the IRB application look like when a short form process is requested?

**A:** Look for 1) a translated form, 2) an English version of the form, and 3) a process description for use of the form on the “Consent Process Page” of the application.
SHORT FORM CONSENT TRANSLATIONS

Q: What is the process for obtaining consent using a translated short form?

A:

1. In the event that a participant does not speak English, the oral presentation will be translated with the use of an interpreter.
2. The written summary of the oral presentation will be the IRB approved long consent document.
3. Hospital-based, professional translation services will be provided to all non-English speaking study participants.
4. Consent will be documented using a short form.
5. A third-party witness will be present during the oral presentation and will sign both the long form and the short form. The witness will be fluent in both English and Spanish.
6. The person obtaining consent will sign the long form.
7. The participant will sign the short form.
8. The participant will receive a copy of the consent form in English and the translated short form.
What are the rules for enrolling students and employees in studies?
BOARD MEMBER RESPONSIBILITIES
What are the responsibilities of secondary reviewers?
**PRIMARY & SECONDARY REVIEWERS**

**IRB SOP 202:** “Each IRB member’s primary duty is the protection of the rights and welfare of the individual human beings who are serving as the subjects of that research.”

**IRB Board Member Manual:** “A primary reviewer is assigned to review the protocol and consent process, and a secondary reviewer is assigned to review the consent process again and in more detail.”
How do I update my **board member profile** in ERICA to show what **vulnerable populations** I can represent?
VULNERABLE POPULATIONS REPRESENTATION

A member should have *extensive* background, education, or experience with the population. This may include:

- A direct affiliation to the population
- Work or life experience with the population
- Research experience with the population
- Holding a certification or licensure that permits the treatment, counseling, or other direct relationship with the population
VULNERABLE POPULATIONS REPRESENTATION

With this type of background, a member would have meaningful experience addressing, understanding, or working within the parameters of the population’s specific vulnerability.

- Children/Neonates are vulnerable because they lack full maturity and psychological capacity to protect their own interests.
- Cognitively-impaired adults are vulnerable because they lack the full psychological capacity to protect their own interests.
- Fetuses are vulnerable because they are subject to the environment of their mothers, which may not be conducive to protection of the fetuses’ interests.
- Prisoners are vulnerable because they lack some social and legal rights to act for themselves to protect their own interests. Additionally, they are subject to the authority of others for much of their action and behavior, thus increasing their vulnerability to coercion.
- Economically or educationally disadvantaged person are vulnerable because they may lack the social, financial, and educational resources, increasing their vulnerability to coercion.
How specific should my “Approve with Changes” revisions be so an IRB Chair can sign-off?
What is the difference between Privacy and Confidentiality?
What is the difference between compensation and reimbursement?
What is the new definition of "Serious Non-Compliance"? How is it different from the old definition?
OLD VS. NEW

FORMER

Serious Non-Compliance is “an act or omission to act that resulted in increased physical, psychological, safety, or privacy risk that compromised the rights and welfare of research participants.”

Serious Non-Compliance is “an act or omission to act that resulted in significant harm (physical, psychological, safety, or privacy) or significantly increased the possibility of harm to the rights and welfare of research participants.”

UPDATED

Serious Non-Compliance is “an act or omission to act that resulted in significant harm (physical, psychological, safety, or privacy) or significantly increased the possibility of harm to the rights and welfare of research participants.”
How have we changed how we review new risks in IBs as they relate to UP determinations?
The IRB defines an **Unanticipated Problem (UP)** as follows:

Any **incident, experience, or outcome** that meets all of the following criteria:

1. **Unexpected** (unforeseen by the researcher or the research participant) in terms of nature, severity, or frequency, given the research procedures and the subject population being studied; and

2. **Related or probably related** to participation in the research, or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; and

3. Suggests that the research places subjects or others at a **greater risk of harm** (including physical, psychological, economic or social harm) than was previously known or recognized.

*IB updated with meta-analysis from several sites/studies ≠ UP*
What is a combination device?
How can I tell if a study has one?
The study I’m reviewing includes a **Humanitarian Use Device (HUD)**. How should I review this? Is it research?
An Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

To obtain approval for an HUD, an humanitarian device exemption (HDE) application is submitted to FDA.

An HDE is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose.

The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.
ANCILLARY COMMITTEES
How many **ancillary committees** are there? What do they review?
The University Human Research Protection Program (HRPP) includes several committees that specialize in regulating a specific aspect of human subject research.

- All of the ancillary committees are automated in ERICA to some degree.
- The IRB is the last stop of this review process.
“Huntsman Cancer Institute Project Review & Monitoring Committee” (formerly the CCIC)

The PRMC was established to provide scientific review for all cancer trials as required by (NCI) Cancer Center Support Grant (CCSG) guidelines.

All clinical trials at the University of Utah that involve cancer patients or subjects at risk for cancer (screening or prevention studies) must undergo an initial review by the PRMC.

Two reviewers with no involvement in the trial under review, a biostatistician, a research pharmacist, a research nurse, and a patient advocate provide written reviews.
ANCILLARY COMMITTEES

“Radiological Drug Research Committee & Human Use Subcommittee”

The RDRC is required to evaluate and to approve or disapprove all research and developmental uses of radioisotopes on or in humans.

As required by Utah Division of Radiation Control, the HUS evaluates and approves or disapproves all proposed uses of ionizing radiation sources on or in humans for investigational or non-routine clinical procedures.
ANCILLARY COMMITTEES

“Utah Resource for Genetic & Epidemiologic Research”

The RGE was established by Executive Order of the Governor of Utah on July 14, 1982, as a “data resource for the collection, storage, study, and dissemination of medical and related information” for “the purpose of reducing morbidity or mortality, or for the purpose of evaluating and improving the quality of hospital and medical care.”

RGE governs access to the Utah Population Database (UPDB), which includes family history records, vital records, cancer registry records, driver license records, and others.

These records are linked together to form multi-generational pedigrees as well as longitudinal person-level data.
ANCILLARY COMMITTEES

“Conflict of Interest”

The Col Office supports the University community in identifying and managing financial conflicts of interest in three areas:
- Research and Scholarly Activities
- Procurement
- Intellectual Property

Col works with faculty, staff, postdoctoral fellows, students and others who are required to disclose external financial interests to the University for evaluation.

They also work with the Individual Conflict of Interest Committee to review and manage financial interests that create conflicts of interest.
**ANCILLARY COMMITTEES**

**“Institutional Biosafety Committee”**

An IBC is required at institutions that receive funding from the National Institutes of Health (NIH) for research involving recombinant or synthetic nucleic acid molecules.

All non-exempt recombinant DNA and synthetic nucleic acid research at the U, regardless of funding source, must be conducted in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and must be registered with the IBC.

At the U, as at many other institutions, the IBC also has the responsibility of reviewing a variety of experimentation that involves biological materials, such as risk group (RG) 2 or higher pathogens, and other potentially hazardous agents, such as biological toxins.
ANCILLARY COMMITTEES

“Primary Children’s Hospital” Privacy Board

The PCH Privacy Board reviews research that includes PCH as a study site to ensure that the study:

- Aligns with Primary Children's Mission, Vision and Values
- Receives approval from the Primary Children's resources impacted (e.g.: lab, radiology, infant unit, etc.); and
- Identifies Primary Children's study related charges from standard of care charges
ANCILLARY COMMITTEES

“Center for Clinical & Translational Science”

CCTS builds on the University’s strengths in genetics and bioinformatics to translate promising bench science into practices that improve human health.

The Center serves as an academic home for clinical and translational research, developing innovative health services for the community and health researchers, and training a new generation of clinical and translational investigators.

The Clinical Services Core (CSC), located on the fifth floor of the U of U Medical Center, serves as the CCTS venue for inpatient and outpatient human subjects studies.

Studies are reviewed by, and must be approved by both the IRB and the CCTS before they may begin. In addition to human subject safety and risk, the CCTS evaluates and scores protocols on scientific merit, feasibility, statistical rigor, likely academic benefit to the institution and investigator, and utilization of CCTS resources.
ANCILLARY COMMITTEES

“Office of Sponsored Projects”

OSP is responsible for preparing, interpreting, negotiating, and executing agreements on behalf of the U for projects funded by federal and state agencies, foundations, and other public and private sources.

They also draft, negotiate, and execute awards and subawards for collaborative research.
ANCILLARY COMMITTEES

“Technology & Venture Commercialization Office” (formerly TCO)

TCO is dedicated to commercializing new technologies and inventions from discoveries made and developed at the University of Utah.

They apply a stage-gated, milestone-driven process that has as an end-goal of licensing intellectual property, building beneficial commercial partnerships, supporting our community and educating students.
ANCILLARY COMMITTEES

“Veteran’s Affairs” (Salt Lake City Health Care System)

The VA Research & Development program seeks to improve the lives of Veterans and all Americans through health care discovery and innovation.

SLC VA R&D personnel review VA research proposals to ensure VA requirements are met.
“University Tracking of Clinical Research”

uTRAC serves to assist researchers with creating a protocol billing grid and budget for their project.

If studies intend to bill insurance for any study-related procedures, a Medicare Coverage Analysis (MCA) must be performed in uTRAC.

All clinical research studies are required to use uTRAC. A study is clinical if it involves one or more prospective clinical procedures, services, or other items. By institutional policy, no exceptions can be made to this rule.