INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

Who Are We?

Ann Johnson, PhD, MPH, CIP
IRB Director

Lisa Rigtrup, BS, CIP
IRB Operations Manager

Anna Shirley, BS, CIP
IRB Administrator

Research Administration Building, 75 South 2000 East #140, Salt Lake City, UT 84112

Moving Beyond Informed Consent Templates
An Interactive, Guided Approach for Investigators

Purpose

The purpose of this project was to develop an alternative method for assisting investigators in writing a consent document instead of the traditional informed consent template. Given recent regulatory changes, a template was an ill-suited approach for addressing the breadth of research designs. This approach offers optimal flexibility to researchers when creating consent documents while meeting regulatory requirements.

Methodology

We created **interactive online guidance and checklists** that allow the investigators to build consent documents based on the type of study they are proposing. We performed an initial evaluation of this new approach through focus groups with the IRB staff and study personnel at the University of Utah and its affiliate institutions. We released the new approach publicly in 2019.

Results

IRB STAFF

We prepared our staff for the changes in advance, and they were supportive of this new approach. They recognized the learning curve that they would have in order to be effective at reviewing consent documents that did not follow a strict template.

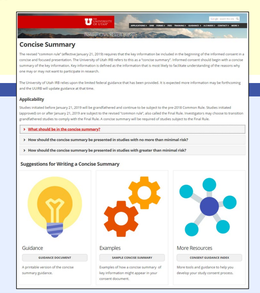
STUDY TEAMS

We received key discussion and feedback from study personnel, including:

- Checklists must clearly identify **when each consent element applies** when using different research designs. This led to the dynamic, interactive nature of the online checklist.
- It was important that the checklists have a clear way to determine **when institutional verbatim language must be used**.
- It may be appropriate for departments or study teams to develop "in-house" consent templates that are specific to the types of research perform regularly, allowing for efficient creation of consent documents.
- It is very helpful for the IRB to provide **model consent documents** that demonstrate acceptable ways consent elements can be designed, worded, and organized. This is especially important for training new researchers and personnel.

CONCISE SUMMARY

There was a need for enhanced guidance on the new Common Rule element of including **key information** of the study at the beginning of a consent document. This resulted in a distinct guidance page for this element, as well as modeled language for different types of studies.



Want to See More?

http://irb.utah.edu/informed-consent