Session Objectives

• Identify common submission screening questions
• Examine IRB-required modifications related to the consent process
• Discuss common post-approval monitoring findings
• Review best practices and available resources
Session Overview

- Regulations
- Screening
- IRB Review
- Post-Approval Monitoring
- Resources
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Informed Consent Overview

- Ethical human subjects research
- “Respect for persons”
- Interactive ongoing process
- Nature and circumstances are important
Federal Regulations

21 CFR Part 50, Informed Consent of Human Subjects

45 CFR Part 46, Protection of Human Research Subjects
Definition

Informed Consent:

• Agreement to participate in research
• Individual or legally authorized representative
• Sufficient information
• Adequate opportunity to consider voluntary participation
Informed Consent Attributes

- Written documentation
- Sufficient opportunity to consider participation
- No coercion or undue influence
- Free of exculpatory language
- Understandable language
Understandable Language

• 12-16% of U.S. adults cannot read

• 22% have basic reading skills

• Target reading level misses one third of audience

FDA Draft Consent Guidance

“…more than one-third of U.S. adults, 77 million people, have basic or below basic health literacy.”

Informed Consent Information Sheet, Draft FDA Guidance (July 2014)
“...more than one-half of U.S. adults have basic or below basic quantitative literacy...”

Informed Consent Information Sheet, Draft FDA Guidance (July 2014)
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Frequent Requests/Questions
Please delete instructions in italicized red font and replace with applicable language. Blue font indicates new elements of consent according to the 2018 Common Rule revisions; please update to black font in the final form version.

The Ohio State University Consent to Participate in Research

Study Title:

Principal Investigator:

Sponsor:

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what...
Please delete instructions in italicized red font and replace with applicable language. Blue font indicates new elements of consent according to 2018 Common Rule updates; please update to black font in final clean version of the form.

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:
Principal Investigator:
Sponsor:

- This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what...
15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;

[Select additional from below, as appropriate]

- Information gathered for this research about:
  - HIV/AIDS
  - Hepatitis infection
  - Sexually transmitted diseases
  - Other reportable infectious diseases
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
  - The diagnosis and treatment of a mental health condition

- Records about any study drug you received;
- Records about the study device; and
- [Add additional items as needed to identify the information in a specific and meaningful manner.]
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Data Collection

• Convened meeting minutes from Biomedical Sciences and Cancer IRBs
  • 6% Continuing reviews
  • 22% Amendments
  • 59% Initial submissions
Data Collection

- March 2019 expedited reviews from Biomedical Sciences and Cancer IRBs
  - 3% Continuing reviews
  - 7% Amendments
  - 8% Initial submissions
CATEGORIES OF CONSENT MODIFICATIONS

- Editorial: 23%
- Costs: 3%
- Payment: 6%
- Key Information: 12%
- Research Methods: 26%
- Lay Language: 16%
- Risks: 14%
Convened vs. Expedited Modifications
Lay Language

Before: We will use a local anesthetic to obtain a skin biopsy from your leg.

After: We will obtain a small sample of skin from your leg after injecting a drug that will numb the area to prevent pain.
Lay Language

Before: The objective of this clinical trial is to assess the efficacy of drug X.

After: The reason for this study is to learn whether drug X helps you get better.
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Fiscal Year 2019 Plan

- Active studies
- 50% randomly selected
- 50% targeted for risks
  - Drugs/devices
  - Federal funding
  - PHI
  - Vulnerable populations
Scope

- 18 monitoring visits
- 7 colleges
Event Report Required

- Yes: 67%
- No: 33%
CONSENT PROCESS

- Procedures completed before consent: 1
- Unapproved method used: 1
- Wrong version used: 5
- Failed to provide copy: 1
CONSENT DOCUMENTATION

Incomplete signature page

Multiple signatures on one form
RECORDKEEPING

- Missing consent document: 2
- Retained only signature page: 1
Session Overview

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Lay Language

- Stanford University Glossary
- Children’s Hospital of Philadelphia Glossary
Consent Process

• Clinical Trial Management Organization (CTMO) Standard Operating Procedure (SOP)
• Consent SOP Example
Summary Overview

- Use correct template
- Insert required text
- Describe research completely
- Distinguish standard care from research
- Use lay language
- Follow consent SOP
- Monitor consent process/records
SCENARIOS
Questions?