Continuing Review under the Revised Common Rule

Ellen Patricia, MS, CIP                      Michael Donovan, MA, CIP
Office of Responsible Research Practices
February 26, 2019
Session Objectives

- Review revised Common Rule changes related to continuing review
- Detail Ohio State’s annual review requirements for human subjects research
- Describe Buck-IRB modifications to accommodate the revised Common Rule
- Discuss case examples
REVISED COMMON RULE
Revised Common Rule Timeline

January 19, 2017
Final Rule issued by Health and Human Services effective date 01/19/18

January 17, 2018
Interim Final Rule announced that delayed effective date until 07/19/18

June 19, 2018
2018 Final Rule issued that delayed compliance until 01/21/19

January 20, 2020
Federally funded single IRB review required
Common Rule Changes

• New/revised definitions
• New/revised exempt categories*
• Informed consent process requirements*
• Consent document posting
• Single IRB Review
• Continuing review requirements

*Recording available
Rationale for Continuing Review Changes

- Easing regulatory burden
- There is limited benefit from continuing review of minimal-risk research
OVERSIGHT
CHANGES
Studies Approved before 01/21/2019

CR
- Federally funded
- FDA regulated
- Greater than minimal risk

ASR
- Minimal Risk
- Eligible for expedited review

Studies Approved before 01/21/2019
Studies Approved before 01/21/2019

Convened IRB continuing review:

- Greater than minimal risk
- Risk level is uncertain (e.g. innovative research)
Studies Approved before 01/21/2019

Expedited IRB continuing review when:

- **Greater than minimal risk and**
  - No participants enrolled (8b) or
  - Long-term follow up (with contact) (8a) and/or
  - Data analysis (8c)
- **Minimal risk and**
  - FDA regulated and/or
  - Federally funded
Studies Approved before 01/21/2019

Annual status report when:

• Minimal risk and
  • Non-FDA regulated
  • Non-federally funded

Note: studies eligible for ASR may no longer be routed through continuing review to allow changes to the research.
Studies Approved after 01/20/2019

**CR**
- FDA regulated
- Greater than minimal risk
- Expedited categories 8b & 9

**ASR**
- Minimal Risk
- Eligible for expedited initial review*

* Other than exceptions noted
Studies Approved after 01/20/2019

Expedited IRB continuing review:

- Greater than minimal risk and
  - No participants enrolled (8b) or
  - Remaining activities involve follow up with participant contact (8a)

- Minimal risk and
  - FDA regulated or
  - Convened initial review (federally funded)
Studies Approved after 01/20/2019

Annual Status Report (No FDA Research)

• Initial expedited review
  • Categories 2-7 (category 1 is FDA-regulated)
    • Expedited categories are to be updated every eight years
    • Presumed minimal risk
Studies Approved after 01/20/2019

Annual Status Report (No FDA Research)

• Initial convened review if:
  • Not federally funded and determined minimal risk (9)
  • Remaining activities involve only:
    • Access and collection of standard clinical data
    • Analysis of identifiable data and/or biospecimens
But…. IRBs can require continuing review if

- The review enhances research subjects’ protection (e.g., investigator noncompliance, unique study), and
- The justification is documented
What happens if I don’t submit an ASR?

Study will lapse similar to continuing review

• Must submit annual status report within 60 days of expiration or new initial submission required
What happens if I submit an FSR and need to access identifiable data/accrue additional subjects?

If within 60 days of study closure, contact ORRP to re-activate study and enable CR/ASR submission.
Case Examples
Case #1

Study involving an FDA-regulated investigational device was initially approved via convened review on December 13, 2018 and determined minimal risk.
Case #1

Study involving an FDA-regulated investigational device was initially approved via convened review on December 13, 2018 and determined minimal risk.
Case #2

Federally funded study involving online surveys and EMR data collection was initially approved on September 24, 2018, under expedited categories 5 and 7.
Case #2

Federally funded study involving online surveys and EMR data collection was initially approved on September 24, 2018, under expedited categories 5 and 7.

CR

ASR
Case #3

Study involving a new surgical technique was determined greater than minimal risk and initially approved via convened review on January 28, 2019. No participants have been enrolled to date.
Case #3

Study involving a new surgical technique was determined greater than minimal risk and initially approved via convened review on January 28, 2019. No participants have been enrolled to date.
Case #4

NIH-funded study involving a new surgical technique was determined greater than minimal risk and initially approved via convened review on January 28, 2019. Enrollment is complete and standard care outcome data are being collected.
Case #4

NIH-funded study involving a new surgical technique was determined greater than minimal risk and initially approved via convened review on January 28, 2019. Enrollment is complete and standard care outcome data are being collected.
Case #5

Federally funded study involving blood and EMR data collection was initially approved on February 25, 2019, under expedited categories 2 and 5.
Case #5

Federally funded study involving blood and EMR data collection was initially approved on February 25, 2019, under expedited categories 2 and 5.
Buck-IRB
Continuing Review/Annual Status Report

System logic
- Beginning (CR or ASR)
- End (CR, ASR, or FSR)

Continuing review pages
- Research Status
- Research Progress
- Number of Participants
- Risk Assessment

Updated CR guide
SUBMISSION TIPS
General

• Submit promptly
• Ensure administrative notes are addressed
• Ensure all study team members have completed CITI training and COI disclosure, including external collaborators with an Individual Investigator Agreement
Continuing Review

• Report overall study status in Research Status
• New funding not requiring revisions may be uploaded
• Ensure accrual consistency with previous year
• Reflect personnel changes in study materials
Continuing Review (cont.)

- Insert Certificate of Confidentiality text if NIH funding and ongoing accrual
- Consider only reportable events when completing Risks section
- Upload all DSMB reports since initial/continuing review
Annual Status Report

• Include accrual total in Research Progress summary
• Amend study to add grant when changes to study materials are needed
“Change can be frightening, and the temptation is often to resist it. But change almost always provides opportunities – to learn new things, to rethink tired processes, and to improve the way we work.” – Klaus Schwab, German Engineer, Economist, Founder and Executive Chairman of the World Economic Forum
Summary Overview

• All studies must undergo annual review
• FDA-regulated research must undergo continuing review
• Buck-IRB will identify the appropriate application
• Plan submission timing to avoid lapse in approval