UCLA ORA Office of Research Administration

OHRPP Updates
Revised Common Rule

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Revised Common Rule

- Released January 19, 2017
- Effective January 19, 2018
- Uncertainty so far
  - Congressional review
  - Administration review
    - October Delay Proposal
    - January Delay Proposal
  - No clarifying guidance
  - Agency variation

So…if it goes into effect…

- Four key changes for you
  - Consent Content
  - Continuing Review
  - Exemptions
  - Single IRB (effective 2020)
    - But NIH mandate effective 2018
- Awaiting further guidance
  - Consent Form Posting
  - Broad Consent
- Changes behind the scenes

How It Affects You…

- Existing studies (approved or certified exempt before 1/19)
  - Stay under pre-2018 regulations
  - Spring ‘18: transition opportunities
- New studies (approved or certified exempt on or after 1/19)
  - Depends on a few factors- we’ll come back to this at the end

Consent Content

- Concise summary of key info
  - Franken-section
  - Short SBER forms already meet
- Additional consent elements
  - Whether or not info/specimens will be deidentified and re-used
  - Whether clinically-relevant results will be provided and how
  - Possible commercial profit from specimens
  - Whole genome sequencing

Consent: What Next?

- OHRPP releasing
  - Updated templates
    - Regulatory changes
    - Certificate of Confidentiality language
    - OHRPP contact information
    - Simplifications and other changes
  - Targeted edits checklist
    - Limited to first 3 items above
- Transition- we'll come back to this at the end

Continuing Review

- Eliminated for studies…
  - Approved via expedited review OR
  - With remaining activities limited to
    - Analysis of data/specimens, or
    - Accessing clinical follow-up data
- …But!
  - FDA and DOJ still require CR
  - IRB can require CR
  - You must still submit amendments, PARs and study closures

Continuing Review

- What will it look like for you?
  - No change to application process
  - New state in webIRB
    - "Approved- No CR Required"
    - No expiration date on approval notice or stamped documents
  - Opportunities to transition existing studies may come this Spring
  - Annual Ping
    - Still working on webIRB changes
    - Reminder of responsibilities
    - Simple confirmation that study active

Exemptions

- Summary
  - New categories
  - Changes to existing categories
  - “Limited IRB review” for certain categories
- What will it look like for you?
  - No outward change yet
  - Staff will start using new criteria
  - Simplified webIRB pathway coming this spring

Your new studies…

Study Characteristics	FDA-Regulated	Not FDA-Regulated
Federal support (except Dept of Justice)	• Consent: New Regs • Continuing Review: No Change • Exemptions: No Change	• Consent: New Regs • Continuing Review: New Regs • Exemptions: New Regs
Dept of Justice support	• Consent: Flex • Continuing Review: No Change • Exemptions: No Change	
No Federal support	• Consent: Flex • Continuing Review: No Change • Exemptions: No Change	• Consent: Flex • Continuing Review: New Regs • Exemptions: New Regs

"No change" means pre-2018 regulations continue to apply

Consent for New Studies

- On or before 3/1 deadline
  - *Consent: New Regs* either:
    - Make changes according to targeted edits checklist
    - Use the new consent templates
  - *Consent: Flex* means:
    - You may use the targeted edits checklist or the new templates
    - But IRB can approve without new requirements

Consent for New Studies

- Any new study submitted after March 1 must use the new consent templates

Takeaways

- You do not need to do anything different now for:
  - Existing approvals/exemptions
  - New Continuing Review rules
  - New Exemption rules
- For new studies:
  - You may need to make targeted edits to consent forms
  - You will need to start using new consent templates (March 1)
- webIRB changes this Spring

Questions?

- Look for announcements today or tomorrow
  - Human Research News
  - OHRPP website
- If delayed, we'll announce in the same places
- Contact special e-mail irbregs@research.ucla.edu or your friendly IRB contacts