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…

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>FDA-Regulated</th>
<th>Not FDA-Regulated</th>
</tr>
</thead>
</table>
| 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 |  • 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