OHRPP Updates

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October 12, 2017

NIH Policy on Single IRBs

- Policy ~~coming this month~~ ***released in June '16***
- Effective for ~~Jan~~ ~~May~~ ~~Sept~~ ***Jan 25, 2018***
- Domestic sites of multi-center
- Proposals to identify cIRB
  - Coordination plans & personnel
  - Certain direct costs allowable

NIH Policy on Single IRBs

- IRBrely SmartIRB framework
  - National agreement now in place
  - 200+ institutions (including UCLA)
  - Some institutions coming up with additional agreements
  - Online tool for communication
- RAND, UC, CTSI+USC, Commercial IRBs, one-offs
  - Commercial IRB scope expanded

NIH Policy on Single IRBs

- Challenges
  - IRB practices are not uniform
  - Institutional Policies
  - Ancillary Reviews
  - Communications among IRBs, IRB offices and study teams
  - Post-Approval Reporting
  - Costing
- Adapting will require extra work and communication

NIH Policy on Single IRBs

- UC-wide workgroups wrapping up, more detailed guidance and tools coming
- For Jan 25 proposals, contact us
  - irbreliance@research.ucla.edu

Final Rule

- Released January 19
- Effective next January (maybe)
- Uncertainty
  - Congressional review period expiry
  - Administration review
  - No clarifying guidance
  - DOJ hasn't signed on
  - FDA hasn't harmonized
  - Other agencies with layers of policy

Final Rule

- On WH docket for 1 year delay
- Proposal to allow flex measures
  - Not officially known
  - No CR for expedited research
  - Some expansion of exemptions
  - No grant congruence requirement

Final Rule

- EVC's HRPB Decisions
  - Replacing Continuing Review
    - Annual Administrative Ping
      - Study active
      - Reminders re amendments, PARs, closure
    - Study will be assumed closed if no response
  - Exemption Determinations
    - Remain with OHRPP
    - webIRB simplifications coming

Certificates of Confidentiality

- What CoCs used to be
- Sudden change
  - NIH only so far
- Coordinating announcement and changes
  - webIRB
  - Consent templates
  - ePass

Certificates of Confidentiality

- NIH-funded projects:
  - human subjects OR
  - very small risk of re-identification
- CoCs automatic
- Responsibilities
  - Protection from subpeona, etc
  - Extra care in releasing info
  - Notifying recipients, sub-awardees
  - Consent (where applicable)

FDA Expanded Access

- Certain categories of expanded access to drugs
- Easier, now along the lines of Emergency Use
  - Concurrence of IRB chair rather than IRB review
- Legal analysis in progress, assessing conflict with state law

Thank you!

- For questions:
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