webIRB Updates

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Landscape

- Federal, state, institutional
- Federal
  - Common Rule
  - FDA
- 2011 ANPRM
- 2015 NPRM
- 2016(?) Final Notice

NPRM

- Goals
  - Improve subject protection
  - Facilitate research
  - Reduce burden
  - Reduce delay
  - Reduce ambiguity

NPRM

- Key Areas
  - Meaningful consent
    - Tighten content requirements
    - Public posting
  - Consent for secondary use
    - Specimens
    - Data
  - Calibrate level of review with risk
    - Rejiggering levels of review
      - Self-certification
    - Continuing Review

NPRM

- Key Areas (ctd)
  - Single IRB Review for Multi-Site
  - Reduce waivers of consent
  - Expand scope
    - Clinical trials regardless of funding

NPRM

- OHRPP Analysis
- Invitation to Research Community
  - PIs might also hear from professional societies
- UC coordinated comment
  - Also via societies

Thank you!

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