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!

❖ For questions:
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