The case for a nonprofit independent IRB – improving the ethical review of research

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About me

• Internal medicine/hematology
• Clinical researcher at NIH
• CIO of the NIH clinical center
• CIO of MaineHealth
• CEO of Western IRB
• Executive Board Chair of Quorum IRB
• PRIM&R and AAHRP Boards
• SACHRP Chair
Importance of IRBs
Importance of IRBs

Knowledge

Science

Business

Ethics

Wealth

Respect
Importance of IRBs

Science

Technology
Knowledge

Business

Wealth
Innovation

Ethics

Respect
Public trust
Importance of IRBs

Science

Tuskegee
Guatemala (Support?)

Business  Ethics
Importance of IRBs

Science

Business

Ethics

Vioxx
Stem Cell Clinics (Boeing 737 Max?)
Importance of IRBs

Science

Business

Ethics

PETA
Over-regulation (GDPR?)
State-of-the-IRB

- Not a learning system
- Opaque
- Quality v. process metrics
- Emphasis on compliance rather than ethics (loss of mission-focus), but...
Recent developments
Recent developments

- Regulations
  - Single IRB mandates
  - Impact on institutional IRBs/HRPPPs
  - Difficulty changing institutional staffing, budgets, processes
- Leadership - change is not seen as mission-driven
Recent developments

- Research
  - Genomics
  - “Big data”
  - Wearables and Apps
  - Citizen science
  - Decedents...
  - And no more “box”

“Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”
Recent developments

• Independent IRBs
  • Investor-ownership
  • Competing fiduciary obligations
  • Consolidation and lack of competition
  • Focus on cost-cutting
  • Little reason to innovate
  • Business Roundtable…
Proposal: nonprofit independent IRB

- Flexibility of a small business *(independent)*
- Fiduciary obligation to research subjects *(nonprofit)*
- Platform for innovation in quality, process, precedent, transparency, inclusion of the participant perspective *(“learning IRB”)*
- and... financially self-sustaining