Preparing for a Streamlined Ethics Review System

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Outline

- Lessons -UK, US, Ontario
- The Road Ahead
- Challenges & Opportunities

UK National Research Ethics Service

- National Health System
- Multi-centre research ethics committees c1997
- Single UK-wide ethical opinion since 2004
- Mandated by legislation
- Online system since 2008

Lessons Learned - UK

- Overly focused at first on system = ↑ focus on people, change management
- Underestimated how embedded investigators were with local REBs = institutional branding removed
- Trust in other REBs = created network of REB chairs
- Patient perspective:
  - Some felt protected by their hospitals and hospital REBs
  - Others thought local REBs were not independent enough

US – UNC Chapel Hill

- Study of central versus local IRB review
- 8 of 20 eligible central IRBs involved
- No major differences in reviews
- Potential time savings of 20 days; more expected
- Now allow use of any UNC pre-approved central IRB (~1/3 of biomedical trials) – not mandatory

CTTI. *Research Institution Perspectives on Advancing the Use of Central IRBs for Multicenter Clinical Trials.* Daniel Nelson. www.ctti-clinicaltrials.org/webinar-series#Research

Lessons Learned - UNC

- The IRB is not the only component of HRPP!!!
  - New processes needed for institutional reviews
- Challenges expected to resolve with experience:
  - consent, multiple processes, communication
- IRB can focus on areas with more "bang for the buck"
- Early advocates didn't want to "leave home"
- Not excuse to outsource "homegrown" single site studies

US – CTTI+ Project*

- Barriers and solutions to using "central" IRBs
- Conflation of institutional responsibilities with ethics review responsibilities of IRB!!!
  - "Considerations" document
    www.ctti-clinicaltrials.org/files/documents/CentralIRBConsiderationsDocument.pdf
- Logistical barriers – different forms & systems
- Trust, liability, quality, local context, loss of revenue

+Clinical Trials Transformative Initiative

*PLOS ONE. January 2013. *Using Central IRBs for Multicenter Clinical Trials in the United States*. Kathryn Flynn, et al
www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0054999

CTTI Project - Recommendations

- Define responsibilities, expectations, communication plans
- Employ change management techniques
- Develop goals, deliverables, measures of success
- Define scope of reliance
- Engage stakeholders
- Communicate. Communicate. Communicate.

Research Institution Perspectives on Advancing the Use of Central IRBs for Multicenter Clinical Trials. Cynthia Hahn
www.ctti-clinicaltrials.org/webinar-series#Research

Lessons Learned – NS-LIJ HS

- Now routinely relies on external IRBs
- Separate institutional and IRB responsibilities!!!
  - Educate everyone on workflow, policies, SOPs
- HRPP workload not lessened, but changed
  - Able to devote more HRPP resources to riskier studies, oversight of research conduct
- Created HRPP fee structure rather than IRB fee – built into study start up and administrative fees

Lessons Learned - OCREB

- Separating institutional responsibilities!!!
- Identifying signatories, department approvers
- Process to delegate to OCREB
  - OCREB/local REB meeting dates; CRA preference
- Tracking studies with OCREB
- "Local context" – consent form language

Lessons Learned - OCREB

- Duplicate entry into institutional review systems & OCREB
- Learning new REB system & processes
- Centres dependent on timing of lead (Provincial) Applicant
- Communication with researchers & teams
- Communication with institution
- Communication with Sponsors/CROs - awareness
- Communication. Communication. Communication.

CTO - The Road Ahead

Responsibilities	CTO	Participating REB	Institution
Communication, stakeholder engagement & change management	**X**	**X**	**X**
eREB system	X		
Legal agreements, including roles & responsibilities	X		
Funding model	X		
Policies & Procedures for CTO ethics review processes	X	X	
REB Qualification	X	X	
Communication plan for sharing information - substantive changes; local context; participant complaints; non-compliance; unanticipated problems; suspension/termination of REB approval	**X**	**X**	**X**
Execute CTO REB authorization/delegation agreement	X		X
Decouple ethics and institutional responsibilities		X	X
Process to manage institutional reviews			X
Maintain MOU & FWA			X
Register CTO REBs under FWA			X
Maintain credentialing of staff			X
Maintain program for education of researchers & staff			X
Maintain policies & procedures for conduct of research			X
Education of REB members and office personnel		X	
Register with OHRP & FDA		X	
Adhere to TCPS2 and to FWA requirements		X	
Ensure research meets accepted ethical standards		X	
Assess researcher qualifications		X	X
Collect, review, site-specific information		X	
Oversight of participating sites		X	
Ensure researcher compliance with REB approved protocol, procedures, documents			X

Challenges

- Aggressive timelines
- Many tasks including significant new processes
- Communication
- Change and resistance to change!!!!
- Two REB systems
- Duplicate data entry (institutional reviews)
- Local context issues (consent language; SOC)

Opportunities

- Collegial collaborations – national, provincial, local
- Ontario leadership – SPOR, CAREB, N2, CGSB
- Common REB application forms
- Consistent REB responsibilities, procedures (policies?)
- Consistent study information for study participants
- Promotes robust HRPP approach = ↑QUALITY
- Necessary. Challenging. Progressive.