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
- Logistical barriers – different forms & systems
- Trust, liability, quality, local context, loss of revenue

+Clinical Trials Transformative Initiative
CTTI Project - Recommendations

- Define responsibilities, expectations, communication plans
- Employ change management techniques
- Develop goals, deliverables, measures of success
- Define scope of reliance
- Engage stakeholders
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
# CTO - The Road Ahead

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