Reliance on Independent IRBs for Multicenter Clinical Trials

David Borasky
Interim Director, Office of Human Research Ethics
University of North Carolina-Chapel Hill

Presentation for Clinical Trials Transformation Initiative (CTTI)
June 12, 2014
Outline

• Background
• New policy and process
• Non-IRB reviews
• Report on Implementation
• Q&A
Background

• Proposed changes to the regulations would mandate single IRB review for multisite studies

• Institutions have been exploring alternative models
  – Typical model involves contracting with single external IRB for industry-sponsored protocols
  – This “sole provider model” has its own problems
    → trades one IRB for one IRB

• UNC signs >300 reliance agreements/yr
Background (Continued)

- Institutional concern that refusal to allow use of central IRB was disincentive for sponsors

- In 2012-13, UNC conducted pilot study
  - Randomized, controlled comparison of local vs central IRB review
  - Assessed feasibility and acceptability of relying on any central/independent/commercial IRB already involved with a multicenter trial, provided certain criteria were met
Pilot Project

• Results
  • Quality of review by central IRBs was good
  • Time savings of ~20 days per trial, if master service agreements already in place
    • Little advantage if no standing agreement
  • 8 central IRBs utilized for 22 protocols randomized to the “experimental” arm
    • Reinforced our hypothesis that “sole provider” model misses many opportunities to streamline
  • Data supported informed policy change
New Policy and Process

• Effective October 15, 2013, UNC will rely on the approval and oversight of the central/independent IRB already involved with an industry-sponsored, multicenter trial, provided certain criteria are met
  – Sponsor/CRO has contracted with independent IRB to provide central review for any/all sites in that study
  – IRB is on UNC’s pre-approved list
Which IRBs?

- Alpha IRB
- Aspire IRB
- Chesapeake IRB
- Compass IRB
- Copernicus IRB
- Ethical & Independent IRB
- IntegReview IRB
- IRB Company
- IRB Service, LTD
- Quorum IRB
- New England IRB
- Schulman and Assoc.
- Sterling
- WIRB

Additional IRBs may be added over time, on request.
What is this NOT?

• Use of central IRB under these circumstances is allowed, encouraged, should be desirable → but is NOT mandatory
  - You still have the option to use UNC IRB

• This is NOT a mechanism to involve a commercial IRB single site studies → These remain under UNC IRB oversight
Interaction with central IRB will shift from protocol review to site registration

(think “add personnel”)
The vast majority of IRB application questions have been suppressed.

Approx 10-20 questions remain, depending on circumstances of individual study.
Other UNC Requirements

• Even when IRB review is “outsourced”
  – UNC is still responsible
  – Other University-based reviews/obligations are not transferred to central IRB and must still be satisfied
    • HIPAA
    • Conflict of Interest (COI)
    • Investigational Drug Service (IDS)
    • Radiation safety
    • Institutional biosafety
    • Data security
    • Institutional consent language → congruence with CTA

• UNC IRB remains central relay station
Submit IRB application requesting reliance on Independent IRB

Receive IRB “stipulation” letter with permission to use Independent IRB & CF injury language

Register site with Independent IRB

Satisfy all Independent IRB & UNC requirements

Respond to UNC IRB stipulation letter

Receive UNC reliance letter documenting permission to begin study
Update on Policy Implementation

- 60 studies since October
- Relying on 11 Independent IRBs - agreements in place with 14
- Time to approval between 30 and 60 days
- Designation of one member of IRB staff as central IRB expert. (Hat-tip to Christina Tyler!)
Implementation Challenges

- Consent form issues
  - Subject injury language
  - HIPAA
  - Stored specimens
- Prolonged communication cycle between sponsor/CRO and UNC OCT
- Resolution of financial conflict of interest issues
- Additional requirements if CRO is submitting to IRB on behalf of PI
Feedback from Research Community

• New processes were difficult to learn
• Need for better tools e.g., instructions, examples
• Time to approval initially frustrating
• Pleased that central IRB applications are much less detailed than UNC’s
• Appreciation the UNC is eligible to participate in more industry-sponsored studies
Next steps

• Refinement of processes

• Development of a training tools for new users

• Ongoing communication between all stakeholders (IRBs, OCT, COI, Sponsors/CROs, etc)
Further information

• Christina Tyler – ctyler@email.unc.edu

• More information on our website:
  http://research.unc.edu/offices/human-research-ethics/relying-on-central-irbs/