Reliance on Independent IRBs for Multicenter Clinical Trials

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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
Workflow

1. Submit IRB application requesting reliance on Independent IRB
2. Receive IRB “stipulation” letter with permission to use Independent IRB & CF injury language
3. Register site with Independent IRB
4. Satisfy all Independent IRB & UNC requirements
5. Respond to UNC IRB stipulation letter
6. 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/