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# Reliance on Independent IRBs for Multicenter Clinical Trials

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# Outline

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

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# 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

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# 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

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# 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

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# 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.*

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# 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

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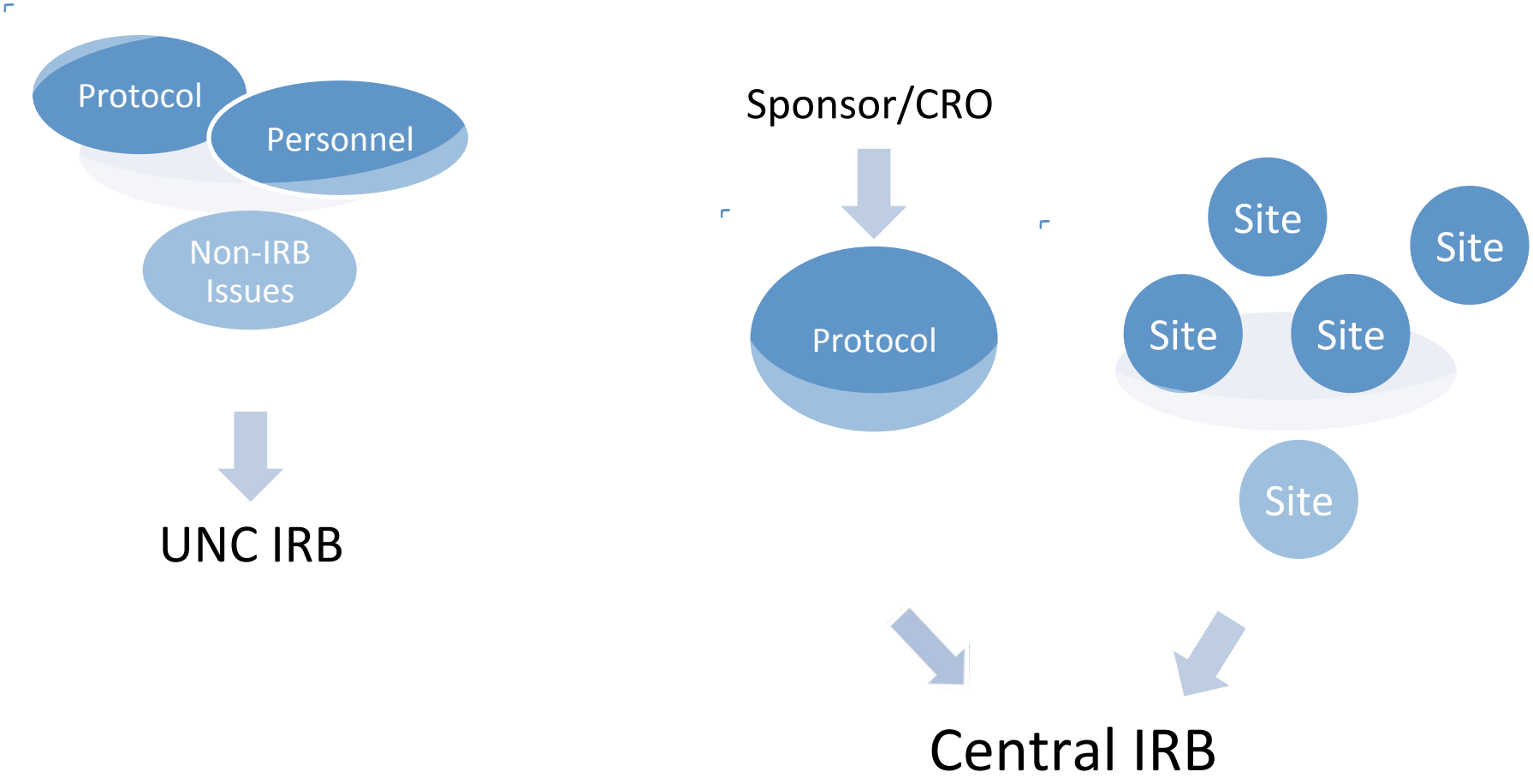
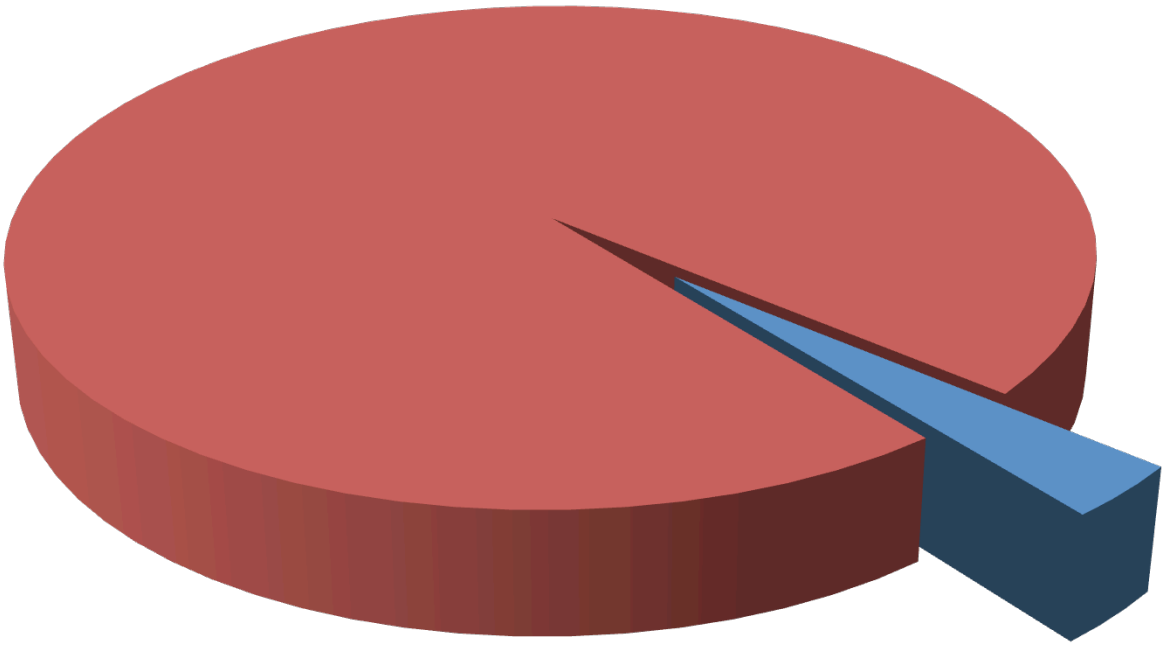
# Interaction with central IRB will shift from protocol review to site registration *(think "add personnel")*



# The vast majority of IRB application questions have been suppressed

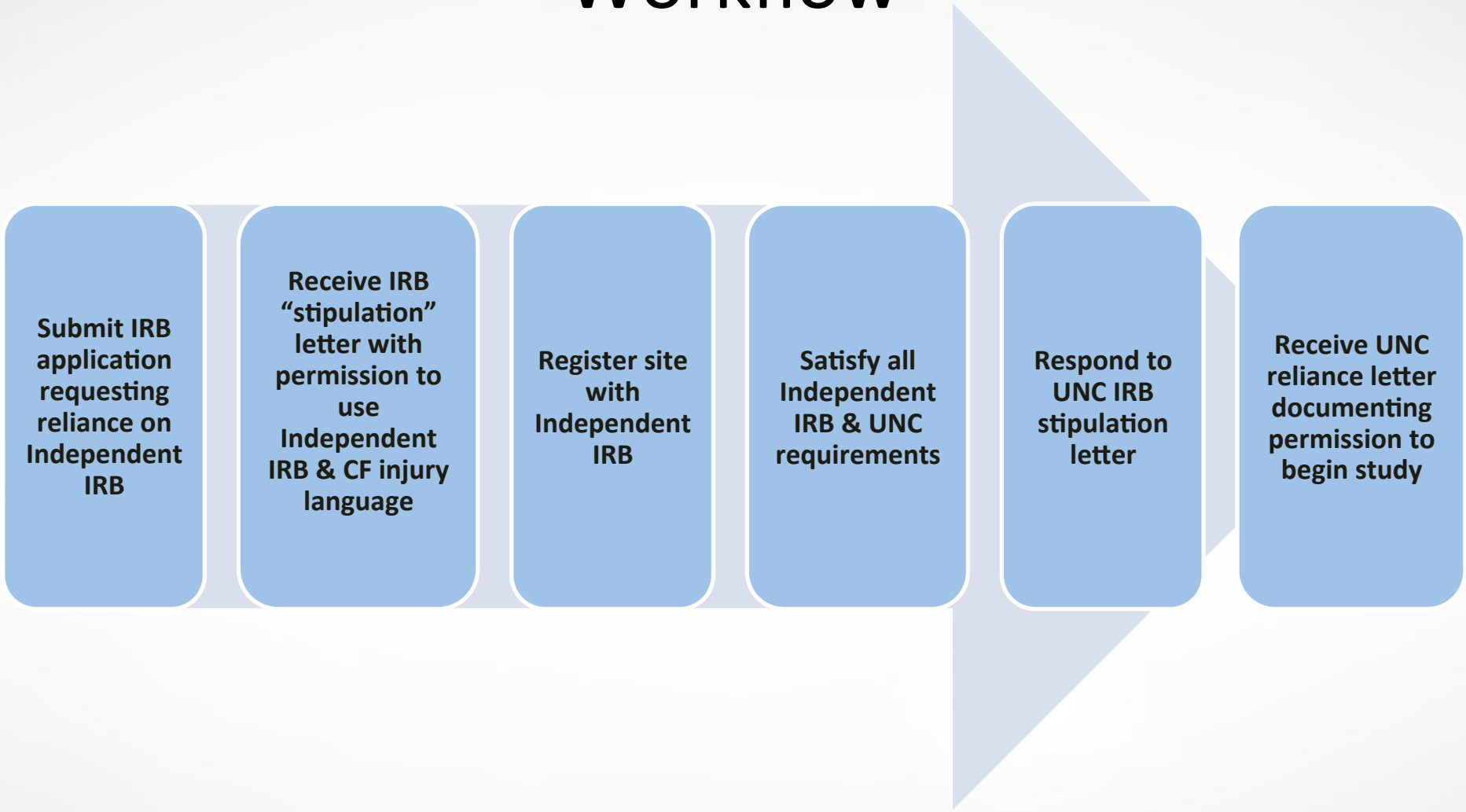


Approx 10-20 questions remain, depending on circumstances of individual study

# 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


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!)

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# 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

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# 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/

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