Ethical and Regulatory Considerations

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Ethical and Regulatory Basics

- Risk/benefit analysis
  - Maximize benefit
    - Is the research worthwhile?
    - Will it have an impact? (Implementation issues)
  - Minimize risk
    - Not only at the beginning of the research…
      - If the research (as initiated) is not working – any risk to individuals is not acceptable
    - If you already know the answer…
- Transparency and honesty
  - Tell participants the facts
    - Interim analyses and possibility of changes or even early termination

IRB Review

- Front-ended
  - The hypothetical (best guess) vs real-life
  - Review includes
    - Study design (aims of the study)
      - If there is more than one aim – say so
    - Context
      - Standard of care
      - Relevant policies
      - Related research
      - Implementation issues

IRB Review

- BUT…ethical and regulatory obligations and assessments do not end with initial IRB approval
  - Circumstances can change
    - Think COVID
    - New relevant policies
    - Informative new research.
    - Study as designed is no longer feasible/doable
    - Interim results support early termination
      - For positive or negative results

What to do

- There is Ethical and Regulatory support to pivot
  - Maximizing benefit
    - E.g., Make intervention available to others earlier
  - Minimizing risk to enrolled as well as potential participants
- But you need justification
  - Study design/statistical verification for change
  - Not simply “errors of enthusiasm”
- Any change to the research needs IRB approval

Challenges

- Multi-site nature of many PCTs
  - Variation in standards of care/practice
  - Variation in local policies (institutional, state, regional)
  - Variation in local resources for implementation
- Single IRB review
  - Difficulty assessing all of the above

Summary

- Pivot with purpose and IRB review and approval

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