

Costs, Timing, and Loss of
Revenue
An Administrator's Perspective

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General considerations:

- Trust
- Liability
- Speed/efficiency
- Local context
- Local control of research agenda
- Administrative burden or relief ?

Costs

- Lack data on actual costs of IRB review
- Clinical trials involve heavy work burden for IRBs and IRB administration
- Economy of scale for large portfolio versus higher costs for smaller operations
- Costs for administration of record keeping and management remain “in-house”

Timing

- Myths about timing
- First time protocol review versus adding investigators or additional sites
- Lack of data on local institutional performance
- Lack of data on performance of alternative mechanisms

Potential Revenue issues

- Cost recovery for requisite internal review and paperwork management
- Loss of revenue to IRB office if review is “outsourced”
- Costs for administration could increase

Questions to ask:

- Why doesn't local IRB perform as efficiently as alternative IRB ?
- What is cost/benefit of outsourcing some or all research review?
- What is goal—increase in access to more clinical trials? -
-Speed?—coordination of effort and reduction of burden?
- Will there be a dual system for review?
- Are some researchers placed at a disadvantage?
- How do we assure that IRBs perform appropriately?
- How much local oversight would be necessary/required?