Mock IRB

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Disclaimer

The views expressed in this talk are ours. They do not represent the position or policy of the NIH, DHHS, or US government.
Estimated incidence of MDR/RR-TB* in 2018, for countries with at least 1000 incident cases

Multi-drug Resistant Tuberculosis (MDR-TB):
TB that is resistant to the two most potent drugs against TB.

Standard-of-Care

• Key aspects of MDR TB Treatment
  – Up to 20 months in length
  – Directly observed
  – Many pills (up to 20/dose)
  • Side effects
  – Pain of injections

IT CAN TAKE

14,600 PILLS TO TREAT

ONE PERSON WITH
DRUG-RESISTANT TB

IF YOU STACK UP THE # OF PILLS END-TO-END

THAT'S EQUIVALENT TO THE HEIGHT OF THE GOLDEN GATE BRIDGE

228 METERS

WE NEED BETTER TREATMENT NOW
STREAM

- International, multi-site, parallel group, open label, randomized controlled trial
  - A: Standard local treatment (WHO approved)
  - B: 40 weeks (kanamycin by injection for 16 weeks)
  - C: 40 weeks (all oral)
  - D: 28 weeks (kanamycin by injection for 8 weeks)
STREAM

• Primary objective of Stage 1: Is Regimen B non-inferior to Regimen A
  – Document health system and patient cost

• Primary objectives of Stage 2:
  – Superiority of C over B (FDA)
  – C is not inferior to B
  – D is not inferior to B
Categories of Research

- Not Human Subject Research
- Exempt from IRB Review
- Expedited Review
  - No more than minimal risk
- Full Committee Review
  - More than minimal risk
Review Process

• Initial Review
  – Research plan
  – Consent documents
  – Advertisements
Review Process

• Assignment
  – Primary
  – Primary/Secondary
  – Subcommittee
Review Process

- Deliberation
- Decision
  - Approve
  - Approve with stipulations
  - Defer
  - Disapprove
IRB Review Criteria

- Risks minimized
- Risks reasonable when compared with anticipated benefit
- Selection of subjects equitable
- Informed consent will be sought
- Informed consent will be documented
- Safety monitoring provision
- *Adequate provisions re: Privacy/Confidentiality*

46 CFR § 46.111