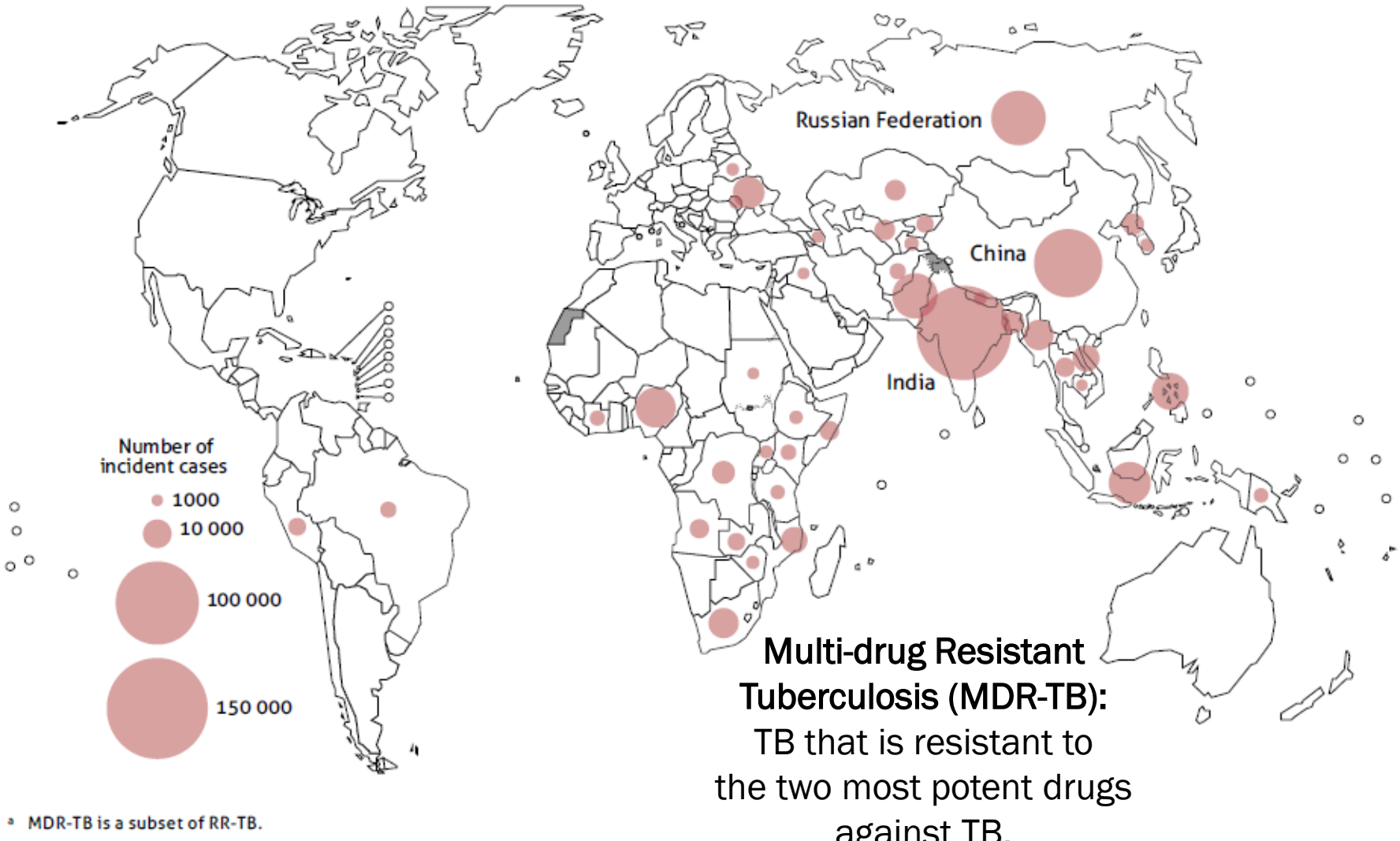
Mock IRB

Joe Millum, PhD, MSc
Department of Bioethics, NIH Clinical Center
Fogarty International Center
Holly Taylor, PhD, MPH
Department of Bioethics, NIH Clinical Center

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[a] in 2018, for countries with at least 1000 incident cases



[a] MDR-TB is a subset of RR-TB.

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

Source: WHO Global TB Report (2018)

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

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