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## Justice: Applied

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# Overview

- Justice considerations relevant at every stage of a research project
  - Choosing a research question
  - Study design
  - Locale of study
  - Recruitment of subjects
  - Dissemination of results

# Principle of Justice: Review

- Moral requirement
  - Equals should be treated equally
- Practical applications
  - Fair allocation of benefits and burdens of research participation
    - ▶ Fair selection
      - Populations
      - Individuals
    - ▶ Unfair allocation may result in exploitation



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## Section A

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Fair Allocation: Population Level

# Fair Allocation: Population Level

- Responsive to health needs
- Subject selection
- Non-exploitation
  - Globalization of clinical research
  - Reasonable availability
  - Overuse of populations

# Fair Allocation: Population Level

- Responsive to health needs
  - Ought to leave population, community better off—or at least no worse off
  - Not enough that disease is prevalent
    - ▶ Engage with appropriate stakeholders

# Fair Allocation: Population Level

- Subject selection
  - Scientific goals of the study
  - Minimize risk
  - Collaborative partnership
  - Available infrastructure
    - ▶ Human
    - ▶ Systems



# Fair Allocation: Population Level

- Non-exploitation
  - Only those likely to benefit from results ought to be considered to be exposed to risk and burden of research enrollment
- Exploitation
  - *A* exploits *B* when *B* receives an unfair level of benefits or unfair burden of risks as a result of interacting with *A*

# Fair Allocation: Population Level

- Globalization of clinical research
  - Since 2002, the number of active U.S. FDA-regulated investigators based outside the U.S. has grown by 15% annually; the number in the U.S. is declining by 5% annually

# Fair Allocation: Population Level

- Globalization of clinical research
  - Reviewed industry-sponsored clinical trials in *NEJM*, *Lancet*, and *JAMA* from 1995 to 2005
    - ▶ Number of countries serving as trial sites outside the U.S. nearly doubled in 10 years
    - ▶ Amount conducted in the U.S. and Western Europe decreased

# Fair Allocation: Population Level

- Globalization of clinical research
  - “A pharmaceutical executive reported that a first-rate academic medical center in India charges approximately \$1500 to \$2000 per case report, less than one-tenth of the cost at a second-tier center in the U.S.”

# Fair Allocation: Population Level

- Globalization of clinical research
  - India is set to have U.S. \$1 billion clinical trial industry by 2010, up from \$200 million in 2007
  - Why companies are drawn to India
    - ▶ Technically competent work force
    - ▶ Patient availability
    - ▶ Low costs
    - ▶ Friendly drug control system

# Fair Allocation: Population Level

- Globalization of clinical research
  - Concerns about increase in clinical trial industry in India
    - ▶ Lack of regulation of private trials
      - Solution—clinical trial registry
    - ▶ Uneven application of proper ethics review and informed consent
      - Solution—expand beyond 40 ethics review committees

# Fair Allocation: Population Level

- Reasonable availability
  - Post-trial access to successful intervention
    - ▶ To whom?
      - Subjects, community, region
        - Avoid undue inducement
      - For how long?
      - At what cost to subject?
    - ▶ Who will be responsible for making intervention available?
      - Sponsor
      - Ministry of Health

# Fair Allocation: Population Level

- Fair benefits
  - Alternative to reasonable availability
  - Framework
    - ▶ Benefits to participants during research
    - ▶ Benefits to population during the research
    - ▶ Benefits to population after research
  - Collaborative partnership
  - Transparency



# Fair Allocation: Population Level

- Fair benefits
  - Alternative to reasonable availability
  - Framework
    - ▶ Benefits to participants during research
    - ▶ Benefits to population during the research
    - ▶ Benefits to population after research
  - Collaborative partnership
  - Transparency

# Fair Allocation: Population Level

- Overuse of populations
  - Community-based research