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# Justice in Research Ethics: International Issues

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# Section A

*Justice and International  
Research: Research Issues*

# Distributive Justice



- ◆ Fair distribution of benefits and burdens
- ◆ Whereas beneficence asks us to balance benefits and burdens overall, justice asks us to balance benefits and burdens to the study community

# Issues: Benefit vs. Exploitation

- ◆ Why is research conducted there?
- ◆ What scientific/research/ethical capacity already exists? What capacity of strengthening will occur?
- ◆ What is the likelihood of future access to successful interventions?
- ◆ What is the likelihood of sustained access to non-intervention research benefits?

# Why Is Research Proposed in the Lesser-Developed Community

- ◆ Scientific/public health justification?
- ◆ That country requested it?
- ◆ Convenience/familiarity: Pre-existing relationship
- ◆ Greater prevalence
- ◆ Question or intervention only relevant to their type of health problems

# Is It Ethically Acceptable to Conduct Research There?

- ◆ How consistent with that country's research agenda?
- ◆ Must be favorable benefit:harm ratio for *that* community
- ◆ Research must be relevant to *their* problems
- ◆ Other less vulnerable community?
- ◆ Cost/expediency relevant but not decisive



# Types of Research Partnerships

- ◆ *Postal research*: Send samples back
- ◆ *Parachute research*: Drop in and collect samples; bring back
- ◆ *Annexed sites*: Expatriate staff direct local, newly developed field sites
- ◆ *Partnership*



# Characteristics of Research Partnerships

- ◆ Local academics manage sites
- ◆ Expatriate academics visit regularly to provide advice/technical support
- ◆ Expatriate junior research fellows work in country with local counterparts, under supervision of local academics

# Cooperative Partnership Relies On

- ◆ Mutual trust
- ◆ National ownership
- ◆ Emphasis on getting findings into policy and practice
- ◆ Development of national research capacity

# Kass/Dawson findings

- ◆ 98% of local researchers are involved in subject recruitment
- ◆ 87% are involved in conception of initial study design
- ◆ 69% are involved in data analysis
- ◆ 53% are involved in grant writing

# Justice Requires Benefit to Study Population/Host Country

- ◆ Must have access to fruits of research; otherwise, it would be exploitation
- ◆ How clear a plan is required?
  - Concrete plans?
  - Findings will fuel ability to advocate?

# What Increases Likelihood of Exploitation? (UNAIDS)

- ◆ Less experience with scientific research
- ◆ Less local infrastructure for health care and treatment
- ◆ Less ability to give voluntary informed consent, due to social, gender, class inequities



Joint United Nations Programme on HIV/AIDS

**UNAIDS**

UNICEF • UNDP • UNFPA • UNDCP  
UNESCO • WHO • WORLD BANK

# What Increases Likelihood of Exploitation? (UNAIDS)

- ◆ Less experience or capacity with scientific and/or ethical review
- ◆ Less infrastructure to conduct own research



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## Section B

*Justice and International Research:  
Collaboration, Capacity Building, and  
What Is Owed to Study Communities*



# CIOMS Guidance About Justice

- ◆ Must be responsive to health needs of host country
- ◆ Disease is an important problem in host country
- ◆ Agree in advance that products will be made reasonably available afterward



# CIOMS Guidance About Justice

- ◆ Develop capacity to carry out similar projects independently, including ethical review
- ◆ Obligations clarified in advance



# Responsive to Health Needs and Priorities of Host Communities

- ◆ Reason for choosing site should be explicit
- ◆ Should not exhaust resources that community “usually devotes to the health care of its members”

# Prior Agreements About Future Access

- ◆ If any product is developed, there must be an understanding before research is begun
- ◆ Sponsoring agency should ensure reasonable availability
- ◆ Must discuss availability of other (non-intervention) services

# Kass/Dawson Study Findings

- ◆ 67% of U.S. investigators said intervention was or would be provided
- ◆ 53% said research should not be carried out unless intervention, if successful, would be made available
  - 46% of those conducting intervention study agreed with this statement

# Researchers' Views

- ◆ “Simply put, the benefits of research conducted in developing countries should also be made available to developing countries at affordable rates as soon as those benefits become apparent”

# Researchers' Views

- ◆ “The issue of what medical care to provide after the study is a thorny one; research can lead to suggested improvements in medical care, but the funding of such improvements, and building of the management skills required to implement them, cannot be the focus of the research. This requirement would mean that chronic illnesses could not be researched, since no funding agency would agree to fund the treatment indefinitely”

# Capacity development

- ◆ “An important secondary objective” is capacity development to carry out similar projects independently
- ◆ Expected to employ and train local individuals to fulfill most roles
- ◆ Should provide facilities and personnel to make health care services available to population from which subjects are recruited



# Kass/Dawson Findings

- ◆ 98% of studies will leave trained personnel
- ◆ 90% leave medical/office/lab equipment
- ◆ 50% leave buildings, lab facilities
- ◆ 43% left power equipment or improved water system or cars

# Obligations of Sponsors

- ◆ Expected to ensure research subjects and communities are not made worse off
- ◆ Expected to provide money to develop capacity for independent ethics review
- ◆ Obligations will vary with circumstances of studies: Clarify in advance

# Glantz, Annas, Grodin, Mariner: Hastings Center Report 28 (1998): 38–42

- ◆ “Research is a means to solving problems, not an end in itself. The goal must be to create interventions that will benefit the people of the countries in which the research is conducted. They will benefit only if the knowledge gained produces interventions that are affordable and accessible. This needs to be determined as a condition of approval before research is conducted so that limited research funds are not wasted, and research subjects are not drawn from populations that will not be able to benefit from the research.” (p. 42)

# Justice Challenges

- ◆ How consistent with national priorities does study need to be?
- ◆ Whose responsibility are dissemination and implementation?
- ◆ What if a study is beneficial to individual participants, but there are no guarantees of future access?
- ◆ What if a study builds capacity, but the benefits provided are not related to the study question?