Developing world research ethics

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Main points

- Principles of research ethics are quite stable. However
  - Their content has been a work in progress for some time
  - Their application is now also a work in progress

Can we ‘use’ human beings in research in order to advance knowledge?

Can we use new interventions directly on the sick without testing them first on human beings?

Research places persons at risk for the benefit of others.

Some implications:
-some chance of this benefit must exist
-some risks are unacceptable
-much of research ethics is about weighing what is acceptable or unacceptable in the face of competing interests.
-conflicts of interest and asymetric relations of power can affect these assessments.
-much of the work of an IEC/IRB is about making these assessments *as if* conflicts of interests and asymetric relations of power did not exist.

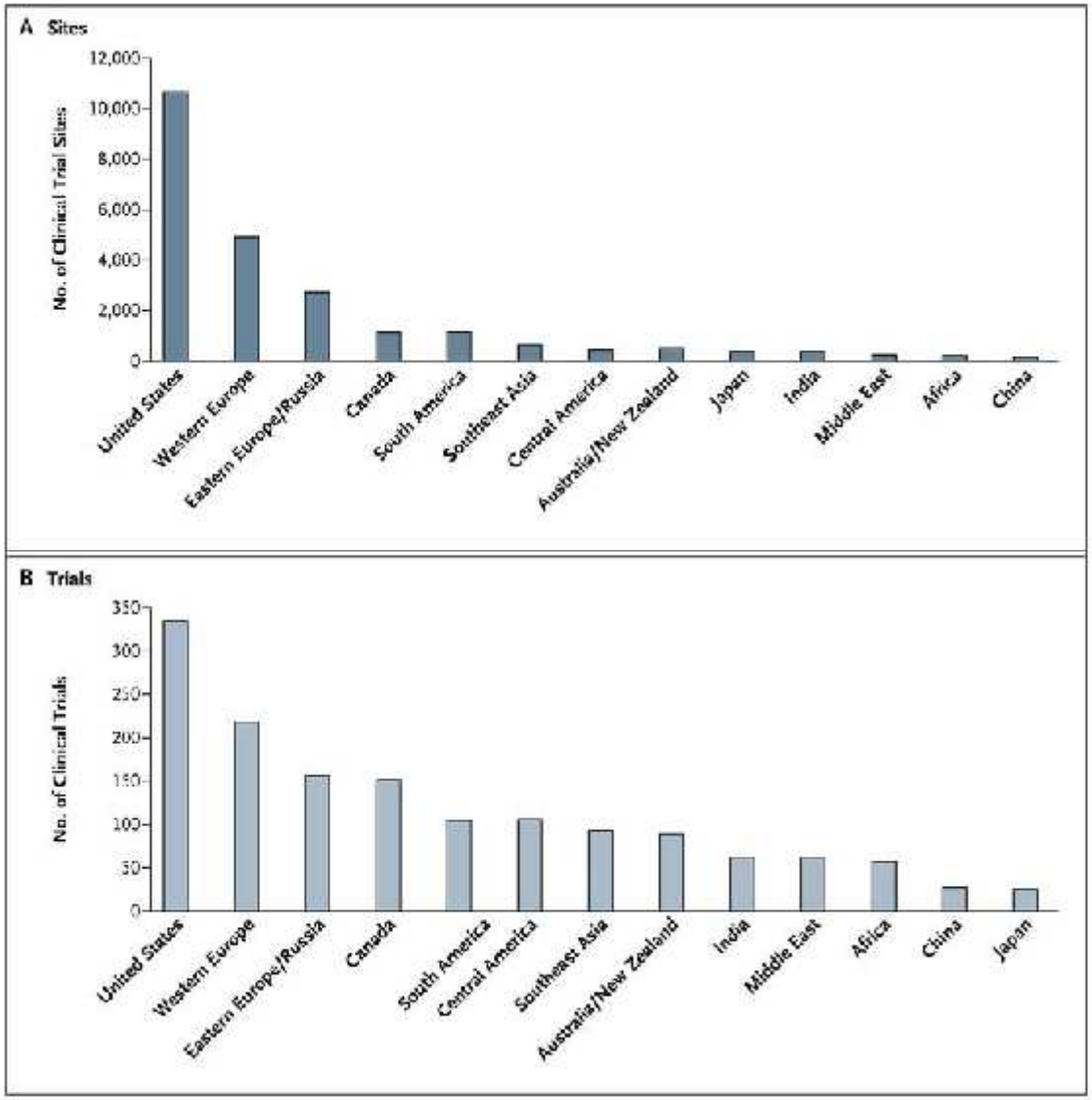


Figure 1 Open Phase 3 Clinical Trials Sponsored by the 20 Largest U.S.-Based Pharmaceutical Companies, as of November 2007.

The size of the pharmaceutical companies is based on total annual health care revenue.9 The number of clinical trial sites (Panel A) includes each location where a study is recruiting patients. The number of clinical trials (Panel B) includes any trial conducted in a country that has at least one site. The data were abstracted from the ClinicalTrials.gov Web site in November 2007.

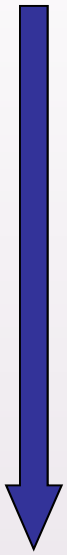
Glickman et al. NEJM 2009; 360:816-823

Benchmarks for ethical research

Collaborative partnership	Social value	Scientific validity	Fair subject selection	Favourable risk-benefit ratio	Independent review	Free and informed consent	Respect for enrolled subjects

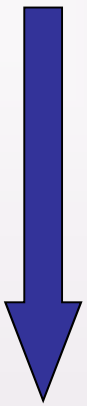
Involve communities:

1) Permission
2) Engagement



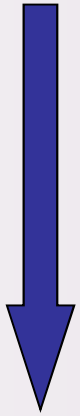
Social value, relevance, *and its distribution,* are important.

Generalisability



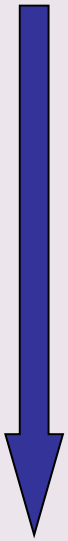
Fair population selection: generalizability, likelihood of benefit from the research.

Local risks, all of them (including risks to communities)



Local review, *and* sponsor country review

Additional safeguards, community permission and individual consent



Confidentiality,' Minimal care' threshold, ancillary care, sharing results

Emanuel, Wendler, Killen, Grady, What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. JID 2004;189:930-7

In short

- International research with human subjects raises distinct difficulties
- It is a setting where applying the usual principles and protections is more difficult
  - deep inequalities
  - asymetrical power relations
  - Cultural differences
  - Lack of capacity
- The principles, however, are the same
  - applying appropriate protections is just as important.
  - And the trend is towards greater enforcement of this.

A few points of current progress

- Requirement for compensation and treatment for research-related injuries (DoH)
- A broader definition of protections for vulnerability (DoH and CIOMS)
- Integration of ancillary care (CIOMS)
- Much capacity building in research ethics

A few points to improve

- Research ethics is not only for doctors (DoH and CIOMS)
  - Currently, international guidelines are non binding to non doctors

A few points to improve

- International coordination in the oversight of research (CIOMS stops just short):
  - Government authorities have the responsibility to ensure competent research and oversight. They should not have sole responsability.
  - Ethics committees should have a coordination mechanism for multi-centre research

A few points to improve

- Giving participants a fair deal
  - The debate about reasonable availability vs fair benefits is not the point. The point is mandating a fair deal.
  - Research is one of these too-frequent cases where we export a practice without exporting its norms, and end-up outsourcing externalities.