Research in developing countries: what are the ethical issues?

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- Independent body that examines ethical questions raised by advances in biology and medicine
- Contributes to policy making and stimulates debate
- Established in 1991
Outline

- Importance of Research in Developing Countries (RDC)
- Why are we concerned?
- What ethical principles apply?
- What ethical issues do we need to consider?
- What has been / should be done?
Key issues

- Importance of countries setting *own* priorities for research
- Genuine consent from each participant
- Appropriate standard of care as comparator in research
- Effective systems for ethical review of research
- Clear agreement in advance about what happens once research is over
Need for research

- Eg.....
- Nuffield Reports 2002/2005
- Bamako call to action 2008
- Crisp 2010
Funding

- Funding priorities:
  - Wellcome Trust
  - Gates Foundation
  - Medical Research Council
  - World Health Organisation
  - European Union
So what is the problem?

- Hastings Center 2009:
  - Research in developing countries poses many ethical challenges, including the need to prevent harm and exploitation of research participants abroad, and to ensure that relevant stakeholders receive a fair share of the benefits.
  - Investment in capacity-building – in particular the quality of ethical review – is a key effort in forging research partnerships with developing countries.
Ethical principles

- Duty to alleviate suffering
- Duty to show respect for persons
- Duty to be sensitive to cultural differences
- Duty not to exploit the vulnerable
Areas of concern

- Setting priorities for research
- Consent
- Standards of care
- When the research is over
- Ethical review
Recommendations

- Priorities to be considered by host and sponsoring countries
- Appropriate information, and consider both community and individual consent
- Ethical review in host and sponsoring countries
- Training and development of ethics review capacity
- Prior agreement on standard of care, with locally available standard the minimum level to be provided, and agreed by research ethics review committee
- Develop local capacity for continuing healthcare
- Prior agreement on availability of treatment post-trial
- Seek agreement for wider post-trial access
Developments

- WHO: Guidance; REC development
- UNESCO: capacity building
- WMA: Helsinki declaration
- NCOB Global Health Symposium 2011
Research in Developing Countries: the central issues remain....

- Need
- Risk
- Capacity
- Principles
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