Ethics in collaborative global health research

Michael Parker

Ethox Centre, University of Oxford
Ethical reasons for doing global research

• Ethics is, at least in part, about what we have good moral reasons to do or to avoid
• There are good moral reasons to do research in developing countries
  – Global health inequalities
  – Disproportionate burden of disease
  – The special value of research in developing countries
• Important to remember that research is not the whole story
• There is a need to complement research with other interventions – social, economic, political
Why collaborate?

• Shift towards collaborative global research:
  – Council of Health research for Development (COHRED, 2000), Ad Hoc Committee on Health Research (1996) and called for networks to address global research disparities
  – Developments in technology and statistical methods and the need for both samples and technology

• Research funding for networks has increased
  • Wellcome Trust Major Overseas Programmes
  • Gates Grand Challenges

• New ethical issues arise because of:
  – Collaboration (south-south/south-north/north-north)
  – Interplay between globalised science and the ‘local’
  – Genomics
Developing good practice in an imperfect world

• What are the ethical obligations of researchers in an imperfect world?

• Poor or absent documentation:
  – When not clear what consent was for
  – When it is not possible to verify that consent has been obtained
  – Samples and data as an important resource
  – The ethics of collecting new samples

• Concerns about imperfect ethics review

• Being realistic about valid consent

• The following slides outline some common ethical issues arising in practice
Valid consent

• Information and understanding
  – How much information required for ‘valid’ consent and who decides?
  – Consent in the context of international collaboration in genomics and data-sharing
  – The need to reach agreement across the collaboration about good consent practice
  – The need for more empirical research on effective, locally appropriate approaches to consent
  – Consent from ‘controls’
Valid consent

• Voluntariness
  – Social and other pressures to take part
  – Voluntariness where researchers are also providing health care or other benefits
  – The therapeutic misconception – confusing research and treatment

• Competence
  – Children and parents of sick children
  – The timing and location of consent

• Community Consent

• What does ‘being realistic’ mean – ethically?
Engaging with communities

- Who or what is the ‘community’?
- What methods of community consultation are appropriate and successful?
- The need for an evidence-base about what works and about what is ethical
- The moral responsibilities of well-established research institutions to the communities they work with
- Tensions between community views and other views about good ethical practice
- Capacity building and training for CABs
Samples

• The use of archived samples
• Deciding whether the consent is valid e.g. for genomics, export, data-release
• Who can approve the use of sample collections?
• When is there a need to re-consent?
• The ethics of not using samples
• The views of IRBs about the international movement of samples
• Ownership or ‘governance’
Why is data-release important?

• For most large funding bodies the depositing of data in a publically accessible repository is a formal requirement.
• It is widely believed that open-access promotes the scientific use and social value of data, and avoids duplication of effort.
• This is embodied in the Fort Lauderdale Agreement.
• It is important to remember that each of these is an empirical claim.
• The Agreement also stresses that open-access can only work against a background of ‘scientific etiquette’.
Data-release: some key issues

• How to promote research of benefit to Africa whilst ensuring that African scientists are not ‘scooped’ by others using their data?
• Ensuring the sustainability of databases requires balancing the interests of data-producers and data-users
• Sustainability requires public trust, appropriate governance and oversight
• How to ensure responsible use of the data at a distance?
• Protecting privacy and confidentiality: is identifiability really a concern? The need for protection without over-protection.
Governing data-release

- Open access or ‘managed open-access’?
- Data-access committees: membership and remit
- The role of data-access agreements: encouraging appropriate uses and users of data and creating obligations e.g. Not to use data in ways which stigmatise populations. Not to try to identify individuals.
- The role of consent in limiting access
- Is there a role for IRBs and communities in setting limits to appropriate uses of data?
- Etiquette: using Fort Lauderdale to protect research areas: what are the appropriate limits?
Data-sharing in collaborations

• The importance of reaching agreement about how data are to be managed and shared in the collaboration
• The value of an ‘internal data management and access policy’
• Sharing data is not enough – the importance of capacity building for local analytical expertise and resources to support local data-analysis
• The importance of supporting both collaborative/consortial research and local research
Global ethics governance

• What is an appropriate approach to the governance of genetic databases and sample collections?
• The role of Ethics Advisory Boards: trust?
• Building the capacity of ethics review. Who should be doing this?
• Does distance between data-producer and data-user lead to a diluted sense of responsibility?
• Training, support and governance-in-practice: the moral world of the scientist
Benefit-sharing and social value

- What is an appropriate approach to benefit sharing in genomics—across the collaboration and with communities?
- What is a benefit in genomics?
- Trust and the importance of community engagement
- Who is a ‘beneficiary’: researchers, participants, communities, future people?
- What does it mean for research to have social value?
Ethics of scientific collaboration

• The importance of trust and fairness in long-term collaboration
• Collaboration often involves a perceived ‘risk’
• Sharing credit appropriately
• Ownership of and fair access to data and samples and maintaining confidentiality
• Authorship
• The key role of capacity-building
Key ethical challenges (1)

• Ethical and social issues can be important factors in successful and appropriate research collaboration

• Identification and analysis of the complex ethical issues arising out of new forms of collaborative research e.g. Emerging infections

• The development of forms of governance capable of addressing the complexities of international collaborative research e.g. sample collection and export, location of bio-repositories.

• The development and evaluation of models of good practice in community engagement
Key ethical challenges (2)

• Clarification of the roles and responsibilities of the various research ‘actors’ in research such as researchers, funders, ministries of health, ethics committees, community advisory boards, field workers, participants.

• The development and evaluation of models and approaches for the achievement of practical solutions to ethical problems arising in diverse real world settings for diverse real-world actors.
Building ethics into science

• Ethical and social issues can be important roadblocks to successful collaboration
• There is value in involving ethics partners in research collaborations
• Ethics partners can work together with researchers to identify, analyse and address ethical issues and can play a key training and policy-development role
• The importance of local and networked ethics capacity i.e. the importance of building local ethics capacity
• Credible ethics is also appropriately critical and independent
• Scientists as moral experts