Ethics

Track C

Gita Ramjee

Research in Developing Countries

- Study participants are often marginalised
  - Residence in developing countries
  - Poverty
  - High HIV infection rate

Need to protect rights of human subjects in developing countries

Key Issues

- Informed consent
- Community participation
- Inducement
- Standard of care

Informed Consent

- Poor understanding of study concepts
- Minimise language and cultural barriers
- Emphasis on education and use of novel methods to ensure understanding
- Informed consent is an ongoing process
- Need to evaluate and monitor informed consent process in clinical trials

Community Participation

- What defines ‘community’?
- Need community representation early and in a sustained manner – design, protocol development and implementation
- Community partnerships is a two-way process
  - Community provide assistance with consenting, phrasing and translation of documents
  - Researchers provide education and improved communication to ensure successful completion of the study

Community Participation cont'd

- Health authorities and stakeholders
- Concerns (Cameroon)
  - Why trials in developing countries?
  - Who gains from research?
  - Provision of post-trial health care?

Inducement

- What defines inducement?
- ‘A can of coke in developing country may be considered inducement?’
- Provision of high quality care in clinical trials = inducement?
- Should trial participants alone be provided high quality care in the community – rest of the community?
- INNOVATIVE STRATEGIES needed to ensure voluntary participation

Standard of Care

- End of trial – care stops – health problems persist
- Moral and psychosocial support – not enough
- ARV not provided to HIV-positive individuals
- PEP – provision of ARV to study staff?
- **NEED TO CREATE PARTNERSHIPS WITH LOCAL HEALTH PROVIDERS, COUNSELLING SERVICES, ETC. DURING PROTOCOL DEVELOPMENT**

Challenges

- There are many ethical challenges in conducting clinical trials in developing countries
- Open and interactive dialogue with all stakeholders (local, national and international) is needed to address complex issues and reach consensus