

# Worksheet

## 'Ethics – Things to Think About'

For each 'Things to Think About' answer the questions given and then ask yourself: 'What role can communities and NGOs play to address these issues?'

- 1. Vulnerable populations** – In order to test if a vaccine works, large numbers of individuals at high risk for HIV infection must be recruited for clinical trials. Who might these individuals be and what rights do they have that need to be protected? (Note: if the vaccine is not effective in preventing HIV transmission then some trial volunteers may well contract HIV.)
- 2. Children and breast-feeding and pregnant women** – In the past children and women have been excluded from trials. UNAIDS has recommended that they now be included to verify safety, immunogenicity and efficacy from their standpoint. What issues need to be considered for the inclusion of women (including breast-feeding and pregnant women) and children in trials?
- 3. Risk-benefit ratio** – potential risks to volunteers should be identified and minimized and potential benefits maximized. The risks to individual participants should be outweighed by the benefits to the individual or society. What potential risks and potential benefits exist for trial volunteers?
- 4. Access to Treatment and Care** – many have argued that vaccine trial volunteers should be provided access to AIDS treatment and care if they become infected with HIV during the trial. Others suggest that offering AIDS treatment and care to potential volunteers in countries where treatments are not currently available may cause people to volunteer for a trial which they may not have done otherwise. Is this coercion or a reasonable incentive? If treatment and care is provided, should it be the best proven therapy, or the highest level of care provided in the host country?
- 5. Early access to HIV vaccines** – Communities that contribute to the development of preventive HIV vaccines should be prioritized for early access to any effective HIV vaccine. This typically means communities that are at high risk of HIV infection, including women, youth, gay/bisexual men, people who use drugs, sex workers, the poor, the homeless, and communities from developing countries. How can this principle be translated into practice?
- 6. Social harm** – trial volunteers may experience social discrimination or hardship as a result of being associated with the vaccine research. What might be the cause of this discrimination or hardship? What can be done to lessen the likelihood of social harm?
- 7. Informed consent** – In order to follow the guide for ethical human subject research, extra steps must be taken to make sure that a potential volunteer understands what it means to volunteer for a clinical trial and that she/he truly agrees to participate. This process is called informed consent. What information and processes should informed consent include to make sure that a volunteer truly understands what is expected of them as a volunteer and what impact it may have on them?