

## **APPENDIX B: KEY TEXTS**

The following are international key texts that have directed the development of these guidelines:

- Nuremberg Code, 1949
- Belmont Report, 1973
- Declaration of Helsinki, October 2000

Some other useful references include:

- ICH Guideline for Good Clinical Practice, ICH Harmonised Tripartite Guideline, May 1997
- International Guidelines for Ethical Review of Epidemiological Studies, Council for International Organisations of Medical Sciences (CIOMS), 1991 Geneva.
- Institutional Review Board (IRB) Guidebook. Office for the Protection from Research Risks – National Institute of Health, USA, 1993
- International Ethical Guidelines for Biomedical Research Involving Human Subjects. Council for International Organisations of Medical Sciences in collaboration with World Health Organisation (WHO). Geneva 2002.
- World Health Organisation 2000. Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva.TDR/PRD/ETHICS/2000.1

Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products. In: The use of essential drugs. Model list of Essential Drugs (Eight List). Sixth report of the WHO Expert Committee. Geneva, World Health Organisation, 1995:97 (WHO Technical Report Series, No 850).