Appendix II: Outline of a manual of procedures for clinical trials

1) Documents
    a) Investigator's brochure
    b) Protocol
    c) Case report forms
    d) Operations manual
    e) Study report
2) Protection of persons
3) Monitoring
    a) Initial visits
4) Serious adverse events
    a) Definition of serious adverse events
    b) Collection, documentation of cases and follow-up
    c) Reporting
    d) Causal relationship
    e) Corrective measures
    f) Crisis management
5) The study drug
    a) Obtaining a standard drug
    b) Double-blind methodology
    c) Packaging
    d) Randomization list
    e) Labeling
    f) Dispatch – Reception
    g) Expiry date
    h) Destruction
6) Data
    a) Coding
    b) Computer entry of data
    c) Tests to validate data
7) Laboratory values
    a) List of compulsory tests
    b) Quality control of assays
    c) Centralized laboratory
8) Development
9) Regulatory affairs
    a) Declaration or request for authorization of a trial
    b) Relations with the competent authorities
    c) Submission for registration
    d) Insurance
    e) Import/export of drugs for clinical trials
10) Miscellaneous
    a) Corrective measures in case a document is lost
    b) Publication
    c) Definitions
    d) Archiving