16.2: Manual of field operations and study diary

The tasks and procedures necessary to achieve each objective of a trial should be listed. A manual of field operations should be prepared, in which each procedure to be carried out is detailed and each task described fully (for example, step-by-step instructions for the administration and completion of questionnaires, the method to be used for weighing infants, including maintenance procedures for the weighing scales, checklists for equipment, and the materials required for each procedure). Each fieldworker should be given a copy of the manual, or of those parts of the manual that are relevant to their work, and these must be updated if changes are made to procedures, as the trial progresses. The field manual for the trial should not only provide a clear set of rules for actions under different circumstances, but it can also serve as a long-term record of the detailed design aspects of the trial. This latter feature may be of special value in trials of long duration where investigators may change or they may forget previous decisions or the reasons for them.

To guard against loss and to facilitate the subsequent search for events of interest, it is recommended that the diary is maintained as a computer file with backups, rather than just in a paper notebook. The latest version of the field manual should also be stored electronically, so that it can be updated and modified easily.