



Office of Research Integrity

U.S. Department of Health & Human Services

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INTERNATIONAL

Data Management Guidelines Issued by British Medical Research Council

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Basic policies on gathering, storing, and retaining research data were issued by the Medical Research Council (MRC) in England for all scientists supported by the MRC as part of its guidelines for good research practice.

The complete guidelines for good research practice, published in December 2000, can be accessed through the ORI web site by selecting "International" in the Resources section and clicking on the MRC link.

The guidelines state that data should be stored in a way that permits a complete retrospective audit and monitored regularly to ensure their completeness and accuracy. Primary data should be retained for 10 years from the completion of the project, but research records related to clinical or public health studies should be retained for 20 years.

The basic policies that apply to notebooks and electronic records follow:

- All raw data should be recorded and retained in indexed laboratory notebooks with permanent binding and numbered pages or in an electronic notebook dedicated to that purpose.
- Machine print-outs, questionnaires, chart recordings, autoradiographs, etc., which cannot be attached to the main record should be retained in a separate ring-binder/folder that is cross-indexed with the main record.
- Records in notebooks should be entered as soon as possible after the data are collected. Recorded data should be identified by date of the record and date of collection if the two do not coincide. Subsequent modifications or additions to records should also be clearly identified and dated.
- Special attention should be paid to recording accurately the use of potentially hazardous substances (e.g., radioactive materials) in both laboratory notebooks and any central logbooks.
- In clinical studies, consent forms should be kept securely with the raw

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data, and normally for the same period of time.

- Supervisors should regularly (monthly or as appropriate) review and "sign-off" notebooks of researchers to signify that records are complete and accurate. Queries should be discussed immediately with the individual who recorded the data and any resultant changes to the records should be signed by both. Authentication of data collected and recorded electronically requires special attention.
- If the data are recorded electronically, the data should be regularly backed up on disc; a hard copy should be made of particularly important data; relevant software must be retained to ensure future access, and special attention should be given to guaranteeing the security of electronic data.



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