



HEI Records Management

Guidance on Managing Research Records

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Introduction

The creation and maintenance of records is integral to the research process. Complete, authentic and reliable records are required to:

- demonstrate good research practice and strengthen the reliability of research evidence;
- safeguard researchers and institutions from allegations of research misconduct;
- demonstrate effective stewardship of resources to auditors and to research sponsors;
- protect individual and institutional intellectual property rights;
- demonstrate compliance with legislation, regulations and other requirements.

All institutions should establish a policy on managing research records to ensure a consistent approach across all disciplines and all types of research. This policy should be supported by detailed procedures to guide and support staff in fulfilling their responsibilities for managing the records associated with, and arising from, their research activities.

This guidance document outlines some of the key issues which institutions should consider in developing a policy on, and procedures for, managing research records.

What are research records?

Records are documents or other items which:

- contain recorded information;
- are produced or received in the initiation, conduct or completion of an activity;
- are retained as evidence of that activity, or because they have other informational value.

The recorded information may be in any form (e.g. text, image, sound) and the records may be in any medium or format, including three-dimensional objects.

Research records – records associated with the research process – can be organised into four categories:

1. Records documenting the research process
e.g. research protocols; applications for regulatory approvals and approvals granted.
2. Records documenting research outcomes or products
e.g. technical reports; monographs.
3. Records documenting the management of the research process/project(s)
e.g. applications for funding; contracts; purchase invoices; staff timesheets.
4. Research data in both 'raw' and 'analysed' form
e.g. notes; completed questionnaires; audio/video recordings; photographs; instrument readings; databases; samples.

The specific types of records in each category vary, depending on the research discipline and the characteristics of projects but some types are common to most research activities (e.g. correspondence (including e-mail), laboratory notebooks).

Who is responsible for managing research records?

Responsibility for managing research records should be clearly defined and documented. It is important to define the responsibilities of:

- staff involved in the research process;
- student researchers and their supervisors;
- staff responsible for supporting the research process.

It is particularly important to define responsibilities for:

- maintaining official (i.e. institutional, as opposed to personal) records of research projects throughout the entire project lifecycle;
- determining retention periods for records of individual research projects, in line with institutional records retention policies;
- maintaining any institutional 'archive' of research records, particularly research data.

The Principal Investigator (PI) is, by default, responsible for the accuracy, completeness and security of all the records produced during a research project. If the PI delegates any responsibilities for managing records to other members of a project team, s/he should define and document these arrangements, and make sure that the other members of the team are aware of them.

Where and how should research records be stored?

Research records should be stored in facilities and equipment ('hard copy' records) or in electronic systems (digital records) which are 'fit for purpose'. 'Fit for purpose' means:

- **adequate space** for all the records which need to be produced and retained;
- **appropriate security measures** to control access to the records;
- **appropriate environmental conditions** for the record media used.

Storage facilities and systems should meet the same standards irrespective of where they are located and who is responsible for managing them.

Designated staff should maintain a record of:

- the content, format and location of all research records;
- research records which have been transferred to another organisation (e.g. returned to a sponsor, deposited in a third-party data archive);
- research records which have been made available (directly by the institution) for re-use/re-purposing by third parties;
- the destruction of research records, including the authority for destruction and the date of destruction.

During a research project, research records should be stored and indexed so that they can be identified and retrieved quickly and easily.

- Paper documents and other 'hard-copy' records should be housed in durable containers which are clearly labelled with key information needed to identify them, and these containers should be stored in secure facilities and equipment. Confidential 'hard-copy' records should be stored in locked equipment or rooms when they are not being used.

- Electronic records should be organised in accordance with institutional protocols for titling, classification and indexing. Confidential electronic records should be protected with passwords and other electronic security measures. If electronic systems are not centrally managed, designated staff should make back-up copies to prevent loss of records through accidental or intentional damage or destruction.

When research records become (relatively) inactive after the completion of a project, they may be transferred to other storage facilities or systems. However, it must still be possible to identify and retrieve them easily and within an acceptable time.

Who should have access to research records?

Access to research records should be controlled to prevent unauthorised use, removal or destruction of the records themselves and unauthorised disclosure of information they contain.

Research records containing personal data must be handled with particular care to ensure compliance with the provisions of the Data Protection Act 1998.

How long should research records be kept?

Some research sponsors specify requirements for retention of specific categories of records. The final section of this guidance contains a summary of the key recordkeeping requirements of the UK Research Councils and other important research sponsors.

Where there are no specific external requirements to retain records of a research project, or when such requirements have already been met, the PI should apply the institution's own records retention policy to the project records.

Research is a complex activity and every project is unique. Applying the institution's records retention policy to the records of an individual research project involves assessing:

- the risks of not having access to evidence of decisions made, actions taken and results produced during the project;
- the benefits of retaining records containing this evidence, for the institution, for the wider academic community and for society as a whole;
- the costs of retaining these records, including the costs of facilities and equipment to store them and of staff to maintain them and provide access to them.

Specific issues to consider in determining retention periods for records of a research project include:

- whether records should be retained to support a patent or other protected intellectual property;
- whether the research has been linked to inquiries or investigations, such as allegations of scientific or financial misconduct;
- whether the research has been controversial or ground-breaking.

Where the nature of the records makes it impossible, or prohibitively expensive, to preserve them for the required or selected retention period (e.g. biological samples), the Principal Investigator should consider what other means are available to preserve the evidence they contain.

How should research records be destroyed?

Research records should be destroyed when agreed retention periods expire. Destruction should be authorised by staff with appropriate authority and should be carried out in accordance with the institution's procedures for destruction of redundant records.

The authority for destruction and the date of destruction should be recorded in the register of research records.

Requirements of Research Funders

This section contains unedited extracts from documents published by UK Research Councils and other research funders, relating to the production and management of research records.

UK Research Councils Core Terms and Conditions for Research Grants

Research grants awarded by the Research Councils are made on the basis of a single set of core terms and conditions. There are separate sets of terms and conditions for grants which fund eligible direct cost plus a contribution to indirect costs (pre-fEC) and those which fund on the basis of 80 per cent of full economic costs (fEC). Both sets are available [here](#). The key section relating to recordkeeping requirements is RG18 (pre-fEC grants) or RG17 (fEC grants):

The Research Council reserves the right to have reasonable access to inspect the records and financial procedures associated with research grants or to appoint any other body or individual for the purpose of such inspection.

The Research Organisation must, if required by the Research Council, provide a statement of account for the grant, independently examined by an auditor who is a member of a recognised professional body, certifying that the expenditure has been incurred in accordance with the research grant terms and conditions.

Research Councils will undertake periodic reviews of Research Organisations within the Dipstick Testing programme to seek assurance that research grants are managed in accordance with the terms and conditions under which they are awarded.

Individual councils may add to these core terms and conditions to reflect the particular circumstances or requirements.

Biotechnology and Biological Sciences Research Council (BBSRC)

<http://www.bbsrc.ac.uk>

BBSRC Statement on Safeguarding Good Scientific Practice (current in December 2006)

Documenting results and storing primary data

- 2.7 Throughout their work, BBSRC requires researchers to keep clear and accurate records of the scientific procedures followed and of the results obtained, including interim results. This is necessary not only as a means of demonstrating proper scientific practice, but also in case questions are subsequently asked about either the conduct of the research or the results obtained. For similar reasons, data generated in the course of research must be kept securely in paper or electronic form. BBSRC expects data to be securely held for a period of ten years after the completion of a research project, and institutions receiving funding from the BBSRC to have guidelines setting out responsibilities and procedures for keeping data.

BBSRC Research Grants – The Guide (November 2006)

5 Resources – Full Economic Costing

Audit requirements for directly incurred costs

Councils expect DI staff to use timesheets so that their actual time is recorded against a project to form the basis of the costs charged. Where a person is contracted to work 100% of their time on a single project (whether they are working full-time or part-time), timesheets are not necessary as their costs can only be charged to that activity. In all other cases, timesheets or project time records are required. This includes those who may be contracted to work on two or more projects, since it is essential when charging to have a means of recording and verifying the actual time applied to each activity. Research Councils' expectations are that time recording will be undertaken regularly and continuously and that records will be verified at least monthly.

Economic and Social Research Council (ESRC)

<http://www.esrc.ac.uk>

ESRC Research Funding Guide (November 2006)

Section 5 – A successful funding application – What happens next?

5.7.4 Vouching and transaction listings

The books, records and financial procedures of the RO shall be open to inspection to the ESRC or any other body or individual engaged by the ESRC for the purposes of such inspection.

Annex C Datasets Policy

The datasets policy reinforces and emphasises the ESRC's stated position relating to the acquisition and use of datasets. The requirements of the datasets policy are now a condition of ESRC research funding. Some key points of the policy for applicants for research funding are outlined below, but applicants are advised to consult the full document which is available from the Secretary to the Research Resources Board.

Dataset deposit requirements

The ESRC supports the Economic and Social Data Service (ESDS) which has responsibilities for the cataloguing and archiving of data. The ESDS is a distributed, yet integrated service which in addition to the key functions of data acquisition, archiving and dissemination, incorporates specialist user support units for Government, Longitudinal, International and Qualitative data. The UK Data Archive (UKDA), which is part of ESDS, is responsible for acquiring, storing and disseminating machine-readable data, quantitative and qualitative, generated as a result of ESRC funding. ESDS Qualidata (which is part of the UKDA) also handles a limited number of qualitative materials that are not in digital format. This involves locating the materials elsewhere for long-term storage, at a relevant specialist repository in the UK.

The ESRC requires all award-holders to offer for deposit copies of both machine-readable and non-machine-readable qualitative data to the ESDS Qualidata unit at the UKDA within three months of the end of the award. This relates not only to datasets arising as a result of primary data collection, but also to derived datasets resulting from ESRC-funded work. These data may be held in one or more formats, for example interview transcripts; diaries; field notes; observational recordings; audio tapes; audio-visual recordings; photographs; press clippings; personal documents, etc. The dataset must be deposited to a standard which would enable the data to be used by a third party, including the provision of adequate documentation. Depositors are advised to contact the ESDS Acquisitions team at the earliest opportunity should the nature of the data be such that it may be difficult to lodge the data with a public repository or archive.

The ESRC will withhold the final payment of an award if any machine-readable dataset has not been deposited to the required standard at the UKDA within three months of the end of the award, except where a modification or waiver of deposit requirements has been agreed in advance.

In order to assist award-holders to deposit their data, the ESRC is prepared to allow a time period within the award, and adequate funding for the preparation of data for archiving. This should be specified in the application and also discussed with the ESDS Acquisitions team at the UKDA when preparing the application.

Applicants who are likely to produce a dataset of any kind as a result of their award are recommended to contact the ESDS Acquisitions team at the UKDA, **prior** to making their

application. From here, applicants can obtain details of deposit requirements so that adequate provision for preparation of data for deposit can be made in the application. The ESDS Acquisitions team will be pleased to offer advice to applicants at this stage. Specifications for the data and documentation are available for both quantitative and qualitative data from the ESDS website. At the time of deposit, the award holder will be asked to sign a licence contract specifying conditions of access, including the degree of confidentiality to be observed in making the data available to others. Enquiries should be addressed to: ESDS Acquisitions, ESDS, UKDA, University of Essex, Wivenhoe Park, Colchester CO4 3SQ.

Should any problem relating to the deposit of the data be foreseen, award holders should contact the ESDS Acquisitions team at the earliest opportunity. Problems may include issues of confidentiality; data ownership; copyright; subject anonymity, etc. It is possible that a request for a modification or waiver of the deposit requirements may be granted by the ESRC, as advised by the Director of the ESDS, should there prove to be a strong case for doing so.

Use of datasets in ESRC-funded research

Any applicant whose research proposal involves funds for primary data collection, or for access to existing datasets, must establish in their application that the required data are not already publicly available. This is to ensure that the ESRC does not duplicate its funding effort, for example, by funding the acquisition of part of a dataset, which is already available from the UKDA or some other data repository. The UKDA holds not only specific datasets, both quantitative and qualitative, but also information about where datasets not held at the UKDA may be found. The ESDS will be pleased to advise applicants on the availability of datasets within the academic community.

ESDS has an extensive set of web pages describing its services, and from which access to the catalogues of data holdings can be gained. These web pages can be accessed at: The ESDS <http://www.esds.ac.uk>

In order to promote awareness of datasets, and encourage their use, the ESRC encourages applicants to cite any datasets used for, or produced as part of, ESRC-funded research in any published materials.

Engineering and Physical Sciences Research Council (EPSRC)

<http://www.epsrc.ac.uk>

Guide to Good Practice in Science and Engineering Research

The Central Role of Data

Primary data as the basis for publications should be securely stored for an appropriate time in a durable form under the control of the institution of their origin.

EPSRC strongly recommends this action. Published reports of cases of scientific misconduct are full of accounts of original data which have disappeared and of the circumstances under which they have allegedly been lost. For that reason alone, the recommendation should form part of EPSRC-funded institutions' procedures to avoid scientific fraud. Additionally, and elsewhere, the council has endorsed the keeping and maintenance of laboratory notebooks, and other data sources, to ensure that intellectual property rights can be protected. The appropriate period for retaining data depends on circumstances (for example, in some fields the importance and relevance of data can be superseded very rapidly). Equally the means of data storage (paper, diskette, CD-ROM, etc) should be appropriate to the task. Even if the individuals responsible for generating the data relocate, a set should be maintained in the institution of origin.

Medical Research Council (MRC)

<http://www.mrc.ac.uk>

Good Research Practice (December 2000, updated September 2005)

4 Conducting the research

4.2 Use, calibration, and maintenance of equipment

Records should be kept of calibration, servicing, faults, breakdowns, and misuse of equipment.

5 Recording the data

5.1 Gathering and storing data

- Confidentiality of personal data is essential¹, including data associated with tissue and biological samples. A Local Research Ethics Committee, Multi-Centre Research Ethics Committee, or other appropriate ethics committee must approve all research involving identifiable personal information or anonymised data from the NHS. All personal information must be encoded or anonymised as far as is possible and consistent with the needs of the study, and as early as possible after collection; ciphers should be held separately. This applies to both paper and electronic records. Detailed guidance is given in separate MRC publications: *Personal Information in Medical Research*² and *Human Tissue and Biological Samples for Use in Research: operational and ethical guidelines*³.
- Data should be stored in a way that permits a complete retrospective audit if necessary.
- Data should be stored safely, with appropriate contingency plans.
- Data records should be monitored regularly to ensure their completeness and accuracy.
- Raw (original) data/images should be recorded and retained (see 5.3 and 5.4); this is especially important where data/images are subsequently enhanced. If possible, both original and enhanced data/images should be stored. Overenhancement or overinterpretation of images must be resisted.
- Confidentiality is also important where there is potential for commercial exploitation (see 7.1).

5.2 Retaining data

Retention of accurately recorded and retrievable results is essential for research.

- Primary research data (and where possible/relevant specimens, samples, questionnaires, audiotapes, etc) must be retained in their original form within the research establishment that generated them for a minimum of ten years from completion of the project.
- Work that informs national policymaking should be archived.

¹ General Medical Council, *Confidentiality: protecting and providing information* (General Medical Council, 2000)

² Medical Research Council, *Personal Information in Medical Research* (Medical Research Council, 2000)

³ Medical Research Council, *Human Tissue and Biological Samples for Use in Research: operational and ethical guidelines* (Medical Research Council, 2001)

- Research records relating to clinical or public health studies should be retained for 20 years to provide scope for longer follow-up if necessary; for detailed guidance see MRC guidelines on Personal Information in Medical Research⁴.
- Researchers who are leaving the establishment that generated the data and who wish to retain data/copies of data for personal use must get permission from their team leader or head of department to do so. Where personal data are involved, the request should be refused unless it is clear that future use will be consistent with the terms of the consent.
- Publication of the data (including in Masters/Doctoral theses) does not negate the need to retain source data.

5.3 Notebooks and electronic records

The following basic policies apply:

- 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 (eg, radioactive materials) in both laboratory notebooks and any central logbooks.
- In clinical studies, consent forms should be kept securely with the raw data, and normally for the same period of time.
- Supervisors should regularly (monthly or as appropriate to the nature of the work) 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 consideration.

5.4 Computer-generated data

Special procedures are necessary for electronically generated data.

- Data should be backed-up regularly; duplicate copies should be held on disc in a secure but readily accessible archive.
- Where feasible, a hard copy should be made of particularly important data.
- Copies of relevant software, particularly the version used to process electronic data, must be retained along with the raw data to ensure future access. Software updates must be logged and stored as new formats and media are adopted.
- Special attention should be paid to guaranteeing the security of electronic data.

⁴Medical Research Council, *Personal Information in Medical Research* (Medical Research Council, 2000)

More comprehensive guidance on the use of electronic systems for data recording and analysis is given in a Department of Health advisory leaflet⁵.

Personal Information in Medical Research (October 2000)

7 Storage and re-use of research data

7.1 Storage

- 7.1.1 Research records need to be preserved for the longer-term for a number of reasons – other than for historical posterity. Firstly, records may be needed later on for scientific validation of research, or for future research and audit. Secondly, occasionally there is a need for access to records over the whole lifetime of patients, both by the patients themselves (who may have continuing long-term concerns about their own health) and their clinicians – for instance, where trials of novel treatments were involved.
- 7.1.2 MRC would expect that research records relating to clinical or public health studies should be maintained for twenty years, to allow adequate time for review, reappraisal, or further research, and to allow any concerns about the conduct or consequences of the work to be resolved. Beyond this date, full records may need to be retained for a few studies only, such as those which were of historical importance, where novel clinical interventions were first used, those which have proved controversial, or where research is ongoing. In the remaining clinical and public health studies, and all other studies for which consent was obtained, a subset of the original records, covering the protocol, the consent procedure, the people who consented to take part,¹⁶ and any records of adverse effects should be retained until thirty years have elapsed.
- 7.1.3 MRC's expectation is that once a research team ceases to exist, when the team leader moves to another centre, or when the team stops working in a particular area, the responsibility for their information passes to the University, Hospital, or research centre. If records are to be stored in the long-term, a custodian must be designated for them, and the custodian's role must include ensuring that information is treated in confidence. If, in due course, the records are to be archived, this should be done in secure repositories. Areas where records may be consulted should be equally secure.

Guidelines for Good Clinical Practice in Clinical Trials (March 1998)

7. Documentation

Appendix 4: Guidelines on key documentation

Clinical Trials Toolkit (developed jointly with the Department of Health)

<http://www.ct-toolkit.ac.uk/>

The Toolkit provides practical help to meet the requirements of the UK Medicines for Human Use (Clinical Trials) Regulations 2004. It contains Route Maps which are designed to help people involved in the management of clinical trials, as well as links to other useful resources. The Route Map for Trial Management and Closure looks at clinical trials from recruitment to data archiving and outlines documentation requirements at each stage. Specifically in relation

⁵ United Kingdom GLP Monitoring Authority, *The Application of Good Laboratory Practice Principles to Computer systems* (Department of Health, 1995)

to data archiving, the following document in the Toolkit relates to the specified requirements in the UK Medicines for Human Use (Clinical Trials) Regulations 2004.

Archiving

Introduction

The documents which individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced, are defined as essential documents according to CPMP/ICH/135/95 [Note for Guidance on Good Clinical Practice].

These documents serve to demonstrate the compliance of the investigator, sponsor and monitor the standards of GCP and with applicable regulatory requirements. They should be filed in an organised way that will facilitate management of the clinical trial, audit and inspection (Trial Master File).

Essential documents must be retained (archived) for sufficient periods to allow for audit and inspection by regulatory authorities and should be readily available upon request.

The Trial Master File should be set up at the beginning of a trial and maintained throughout the trial. Archiving applies to both the investigator sites and the central trial co-ordinating office.

1. Storage

Essential records should be maintained in a legible condition. Prompt retrieval should be possible. Plans for archiving trial documents should be made in the design phase of a trial and costs of storage should be considered. Adequate and suitable space should be provided for the secure storage of all essential records upon trial completion. The facilities should be secure, with appropriate environmental controls and adequate protection from fire, flood and unauthorized access. The storage of the sponsor's documentation may be transferred to a sub-contractor (e.g. a commercial archive) but the ultimate responsibility for the quality, integrity, confidentiality and retrievability of the documents resides with the Sponsor (CPMP/ICH/135/95, 5.2.1). This means that the Sponsor should audit the site and satisfy itself and document that the storage is appropriate.

Access to archives should be restricted to authorised personnel. Any change in the ownership and location of the documentation should be documented in order to allow tracking of the stored records.

An archive index/log should be maintained to record all essential documents that have been entered into the archive, and to track and retrieve documents on loan from the archive.

The investigator should make the Sponsor/trial organisers aware of the storage arrangements for the documents to be stored at investigator sites. If the investigator becomes unable to store their essential documents, the Sponsor/trial organisers should be notified in writing so that alternative storage arrangements can be agreed. If the investigator is no longer able to maintain custody of their essential documents, the Sponsor/trial organisers should be notified in writing and the investigator/institution see to it that appropriate arrangements can be made.

Storage of personal data is subject to applicable elements of EU Directive 95/46/EC and the Data Protection Act 1998.

2. Duration of archiving

The Sponsor/someone on behalf of the Sponsor should consider whether the results of a trial will or may be included in a marketing authorisation application and should take the necessary steps to ensure appropriate retention of the essential documents (see Trial Master File).

Consideration of site specific archiving requirements, as detailed by each R&D Department, is essential as these may differ from those outlined below.

a. Trials which are not to be used in regulatory submissions

Essential documents of the Sponsor/trial organisers and investigators, from trials that are not to be used in regulatory submissions, should be retained for at least five years after completion of the trial. These documents should be retained for a longer period if required by the applicable regulatory requirement(s), the Sponsor or the funder of the trial.

b. Trials to be included in regulatory submissions

i. Sponsor's responsibilities

The Sponsor/someone on behalf of the Sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country(ies) where the product is approved, and/or where the Sponsor intends to apply for approval(s).

The Sponsor-specific essential documents should be retained until at least two years after the last approval of a marketing application in the EU. These documents should be retained for a longer period if required by the applicable regulatory requirement(s) or if needed by the Sponsor.

The requirements of Annex 1 to Directive 2001/83/EC shall be complied with.

In addition the GCP requirements CPMP/ICH/135/95 apply.

ii. Investigator responsibilities

Essential documents should be retained until at least two years after the last approval of a marketing application in the EU. These documents should be retained for a longer period however if required by the applicable regulatory requirement(s) or by agreement with the Sponsor. It is the responsibility of the Sponsor/someone on behalf of the Sponsor to inform the investigator/institution as to when these documents no longer need to be retained.

In addition the requirements of Annex 1 to Directive 2001/83/EC shall be complied with.

4. Destruction of essential documents

The reasons for destruction of essential documents should be documented and signed by a person with appropriate authority. This record should be retained for a further five years from the date that the essential documents were destroyed.

The Sponsor/someone on behalf of the Sponsor should notify investigators in writing when their trial records can be destroyed.

Natural Environment Research Council (NERC)

<http://www.nerc.ac.uk>

Research Grants Handbook (November 2006)

Section D - General Terms and Conditions - Data Availability

131. NERC believes that datasets collected as a result of projects are an important resource that must be adequately managed. Investigators should therefore make sure that a NERC Designated Centre (see Section L) is aware of any significant datasets to be compiled as a result of their projects, so that the long-term future of these data can be planned. At the end of an award Investigators are required to offer the appropriate Data Centre a copy of any dataset generated, so that the data can be made available for other researchers. The Intellectual Property Rights to the data need not be transferred.
132. NERC reserves the right to access all unpublished papers, records, data or collections resulting from the work carried out under a grant, some of which may be required to be deposited with NERC. Similarly NERC reserves the right to use information on the outcome of awards to report on achievements e.g. in annual reports. NERC may, at any time, require detailed information on the results of work funded through grants for use in scientific or financial audits.

Section E – Financial Conditions - Inspection

201. NERC reserves the right to have reasonable access to inspect the records and financial procedures associated with research grants or to appoint any other body or individual for the purpose of such inspection.

Section G – Monitoring and Reporting

262. In general, publication in refereed scientific journals and publication of datasets (e.g. through their deposition with a NERC Data Centre) is the most appropriate way to report and disseminate the findings of a NERC-funded research grant project. NERC is also keen to encourage dissemination to users of science and to non-scientific audiences (see Sections H and J). In addition NERC has specific reporting requirements.

Section I – Publication of Work - Data Availability

284. NERC reserves the right of access to all unpublished papers, records, or collections resulting from the work carried out under an award, some of which may be required to be deposited with NERC. Similarly NERC reserves the right to use information on the outcome of fellowships, grants or studentships in annual reports, strategic plans, and for scientific and financial audit, and may from time to time require current and former award holders to provide detailed information on the results of work funded.

Section L – NERC Designated Data Centres

326. It is NERC policy that recipients of NERC funding must offer to deposit with NERC a copy of datasets resulting from the research, for use by other bona fide researchers, but without prejudice to the intellectual property rights of the originator of the data.

Also see the NERC Data Policy Handbook, Version 2.2 (December 2002)

<http://www.nerc.ac.uk/research/sites/data/policy.asp>

Particle Physics and Astronomy Research Council (PPARC)

<http://www.pparc.ac.uk>

Research Grants Handbook (current in December 2006)

1.3 Accountability

Research Organisations in receipt of research grant funds are expected to ensure that their grant expenditure records will allow a reasonably convenient inspection of the direct charges to grants during the course of a dipstick visit.

Safeguarding Good Scientific Practice (1998)

A joint statement by the Director General of the Research Councils and the Chief Executives of the UK Research Councils (December 1998)

2.6 The Central Role of Data

Primary data as the basis for publications should be securely stored for an appropriate time in a durable form under the control of the RO of their origin.

European Science Foundation

www.esf.org

Good scientific practice in research and scholarship (December 2000)

Data accumulation, handling and storage

36. Data are produced at all stages in experimental research and in scholarship. Data sets are an important resource, which enable later verification of scientific interpretation and conclusions. They may also be the starting point for further studies. It is vital, therefore, that all primary and secondary data are stored in a secure and accessible form.

37. Institutions must pay particular attention to documenting and archiving original research and scholarship data. Several codes of good practice recommend a minimum period of 10 years, longer in the case of especially significant or sensitive data. National or regional discipline-based archives should be considered where there are practical or other problems in storing data at the institution where the research was conducted.

The Wellcome Trust

www.wellcome.ac.uk

Guidelines on Good Research Practice (November 2005)

8 Primary data/samples

- There should be clarity at the outset of the research programme as to the ownership of, where relevant:
 - data and samples used or created in the course of the research
 - the results of the research.
- Researchers should keep clear and accurate records of the procedures followed and the approvals granted during the research process, including records of the interim results obtained as well as of the final research outcomes. This is necessary not only as a means of demonstrating proper research practice, but also in case questions are subsequently asked about either the conduct of the research or the results obtained.
- Data generated in the course of research should be kept securely in paper or electronic format, as appropriate. The Trust considers a minimum of ten years to be an appropriate period, but research based on clinical samples or relating to public health might require longer storage to allow for long-term follow-up to occur.
- Back-up records should always be kept for data stored on a computer.
- Institutions should have guidelines setting out responsibilities and procedures for the storage and disposal of data and samples (including compliance with the requirements of any ethics committee).

The Lancet

Information for authors - What happens after publication? - Data storage (current in December 2006)

<http://www.thelancet.com/authors/lancet/authorinfo>

At any time up to 5 years after publication of research in the journal, authors may be asked to provide the raw data.