

MRC
Medical Research Council

Good Research Practice

MRC Ethics Series

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1 Introduction and scope

The MRC expects **all** scientists, both clinical and non-clinical, funded by the Council (ie, MRC employees, visiting workers in MRC establishments, and recipients of MRC grants or training awards) to adopt the highest achievable standards in the conduct of their research. This means exhibiting impeccable scientific integrity and following the principles of good research practice.

The MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct is published separately.[1] This booklet outlines the key elements of good research practice, setting out the principles that should be taken into account when planning and conducting research, and likewise when recording, reporting, and applying the results.

The seven principles of public life outlined by the Committee on Standards in Public Life (Nolan Committee) in 1995 provide a good starting point:

- selflessness
- integrity
- objectivity
- accountability
- openness
- honesty
- leadership

Other MRC guidance[2] sets out the scientific and ethical principles underpinning the conduct of research; this guide is about ensuring that these principles are achieved in practice.

The Department of Health's Research Governance Framework (in draft, publication expected in 2001) addresses the need to clarify responsibilities for initiation, conduct, and oversight of research conducted within the NHS at organisational as well as personal levels.

Although these guidelines are primarily for scientists supported by the MRC, we hope that other researchers, and those involved in reviewing or supervising research, will find them helpful.

2 Principles

2.1 General principles

Good research practice (GRP) is essentially an attitude of mind that becomes an attitude to work. It is about the way in which research is planned and conducted, the results are recorded and reported, and the fruits of research are disseminated, applied, and exploited. GRP will allow ready verification of the quality and integrity of research data, provide a transparent basis for investigating allegations of bad practice or fraud, and lead to better research. While the integrity and responsibility of individual researchers are of the utmost importance, research institutions, research funders, and the research community in general also share responsibility for promoting and verifying good practice, especially through their arrangements for training and supervision and through the ethos they create.

In clinical studies, the rights, safety, and wellbeing of participants must be safeguarded. Issues of consent and confidentiality are paramount. For clinical trials, the MRC has published separately *MRC Guidelines for Good Clinical Practice in Clinical Trials*, to which researchers should refer.[3]

For near-market projects sponsored by industry and some other funders, the more rigorous requirements of Good Laboratory Practice may be mandatory.[4] There must be adequate resources to accommodate these requirements and further advice should be sought from those with relevant expertise.

Investigational therapeutic products should be manufactured, handled, and stored in accordance with Good Manufacturing Practice[5] or other appropriate guidelines for the manufacture of medicinal products.

GRP can only be achieved if staff at all levels are trained and supervised properly in a research culture that encourages frank discussion and debate. Research team leaders are responsible for seeing that a constructive atmosphere prevails and must ensure that staff have the appropriate training and experience to carry our their duties as effectively as possible; this is especially important for new staff.

To ensure the quality of research practice, supervision and checking are an integral part of the process; a senior member of each research group should take personal responsibility for this. The steps that may be needed to supervise GRP include monitoring of training and supervision of new staff and of continuing professional development, regular checks on data recording and notebooks, and occasional checks on the day-to-day conduct of experiments. From time to time and randomly, experiments should be tracked back from conclusion to conception to ensure that all necessary paper/electronic "trails" are in place.

2.2 Conflicts of interest

Conflicts of interest happen in all walks of life; medical research is no exception. A conflict arises when a person's judgement concerning a primary interest, such as scientific knowledge, could be unduly influenced by a secondary interest, such as financial gain or personal advancement. There is nothing inherently unethical in finding oneself in a position of conflict of interest; what is required is to recognise the

fact and deal with it accordingly.[6] Researchers must pay as much attention to perceived and potential conflicts of interest as to actual conflicts. How one is perceived to act influences the attitudes and actions of others, and the credibility of scientific research overall.

Conflicts of interest can occur at every stage of the research endeavour – from planning the research to disseminating and exploiting the results – and in many forms. Apart from financial interests, conflicts might, for example, be personal, academic, or political. Researchers should automatically ask themselves "Would I feel comfortable if others learnt about my secondary interest in this matter or perceived that I had one?" If the answer is no, the interest must be disclosed and addressed appropriately, for example according to the policy of an employer, a peer-review body, or a journal.

3 Planning the research

All research projects, both clinical and non-clinical, should be conceived, designed, and implemented according to the highest standards, including:

- Clear documentation of the rationale for the study and any subsequent modifications – typically in laboratory notebooks or, for more complex projects, in well-kept files. Each key document and any changes should be signed and dated by the researcher responsible to establish the provenance of the study and protect intellectual property rights.

- Adherence to current safety practices, ethical standards, and law.

- Securing all necessary ethical review and regulatory approvals in good time, for example from Local Research Ethics Committees or the Home Office.

- In clinical studies, identifying a health professional who will take overall responsibility for the well-being and interests of patients or healthy volunteers involved and for ensuring that their rights (eg, in terms of consent and confidentiality) are protected.

- Identifying the individual or group that will take ultimate responsibility for overseeing the scientific and ethical conduct of the study as the scientific plans are put into practice. This is especially important in projects affecting patients or volunteers and in other complex and collaborative programmes.

- Consultation with patients or other beneficiaries/consumers wherever appropriate, especially in clinical and applied research.

- Consultation with statisticians at the planning stage, where relevant. The statistical power of a study should be an early consideration, and researchers should draw on professional statistical advice if needed. This is especially important for studies involving people or animals to avoid unnecessary or unproductive experiments.

- Ensuring that organisations responsible for the care of any patients involved are aware that the research is being planned.

- Assessment of resources needed (eg, space, staff, funding, biological resources, facilities, and clinical support) to ensure the study is viable within the available means.

- Economy in the use of resources, for example not purchasing more reagents than are needed for the planned sample size and regular review to determine when to stop experiments.

- Regular review of progress so that new findings can be taken into account and the project plan modified accordingly, especially if plans involve any risk to participants or use of animals.

- Agreement in advance on who will be writing any planned publications and the authorisation required to publish (see 6.1).

- Acknowledgement of formal or informal contributions to the work, including sponsoring organisations and scientific collaborators.

4.1 Information and organisation

The legal and ethical requirements relating to human participants, animals, and personal information should be familiar to each person involved in the study, and they should know to whom to turn for advice. Since ethical issues, guidance, or requirements often change, research teams and centres must have effective arrangements for disseminating knowledge and documents. Each person should also know when changes may call for new ethical/regulatory approval and should be able to recognise unforeseen results or incidents that need to be reported and discussed.

4.2 Use, calibration, and maintenance of equipment

Equipment used to generate data should be appropriately located, safe, suitable for the purpose, of appropriate design, and of adequate capacity. It should be calibrated and serviced regularly by trained staff so that performance is optimal and the results can be trusted. A designated person should be responsible for ensuring the proper use and maintenance of equipment and, where appropriate, for training staff in its use; when this is not possible, the users themselves should take on the responsibility. Records should be kept of calibration, servicing, faults, breakdowns, and misuse of equipment.

A standard operating procedure (see 4.5) should be maintained for each piece of equipment; in some cases this might be the manufacturer's instruction manual. There should be easily accessible instructions for the safe shutdown of equipment in case of emergency.

4.3 Risks of research misuse

In progressing their scientific investigations, researchers should actively consider any risks that their research will generate outcomes that could be misused for harmful purposes. Where such risks exist, they should seek advice from their Head of Department or Institution and take active steps to minimise them. Units and other institutions should have in place mechanisms to ensure that risks of misuse associated with ongoing research programmes are identified and managed, and to provide advice to the researchers on these issues.

4.4 Hazardous processes and materials

Experiments should be conducted in accordance with MRC and/or local policies on training, and health and safety regulations and guidelines. Where appropriate, risk assessments complying with the regulations on Control of Substances Hazardous to Health (COSHH) should be prepared before the work is carried out. Where necessary, materials and equipment should be decontaminated according to specified health and safety practices including an approved risk assessment. Waste should be disposed of and recorded in accordance with these practices and the appropriate health, safety, and environmental regulations, and also in compliance with local rules for dealing with spillages. Where relevant, the appropriate authority should be notified. Staff should be properly trained and monitored so as not to endanger themselves, others, or the environment.

4.5 Standard operating procedures

Standard operating procedures (SOPs) should be documented for all routine methods and

for individual items of equipment (see 4.2) to ensure that data are collected consistently and accurately. When there is more than one approved technique for any given procedure, all should be covered by SOPs. SOPs should be written in simple language, readily accessible, and ideally in a standardised format. They should be updated as necessary, and only the current version should be available.

Standard written protocols should also be available covering the process of seeking informed consent from patients or volunteers, to ensure clarity and consistency. Written protocols are likewise essential for ensuring strict adherance to regulations/licences, for example in research involving animals.

5 Recording the data

5.1 Gathering and storing data

- Confidentiality of personal data is essential,[7] 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*[8] *and Human Tissue and Biological Samples for Use in Research: operational and ethical guidelines.*[9]

- 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 over-interpretation 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.

- 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 Research*.[8]

- 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.

More comprehensive guidance on the use of electronic systems for data recording and analysis is given in a Department of Health advisory leaflet.[10]

6 Reporting the results

Once any issues of confidentiality and ownership have been addressed (see 7), research findings should be disseminated so that they can be assessed by scientific peers and more widely. This is essential if scientific knowledge is to be used appropriately and effectively. Accordingly, researchers should publish their data in a timely fashion in a peer-reviewed journal or in other equally reputable publications and/or present their results at scientific meetings.

It is equally unethical not to report results, or to exaggerate the importance of results for medical practice or policy. Both are areas in which a researcher's desire for advancement or recognition may conflict directly with the public interest in a complete, balanced, and rigorous account of the scientific evidence.

6.1 Publication policy

- The person with overall responsibility for the research programme should authorise publication of results; authorisation should cover both the content of the paper (integrity of results, adequacy of internal peer review, appropriate protection of intellectual property rights, appropriate authorship) and the intended place of publication.

- Research findings with substantial implications for clinical practice or which are likely to attract strong public interest should be drawn to the attention of the MRC and/or other research funders before publication.

- A written agreement should be negotiated with external sponsors before the research is initiated to cover the free dissemination of research findings; this is especially important where funding has been secured from industry.

- Published reports should normally contain basic information about the ethical acceptability of the work and/or its legality, as well as information about the scientific method.

- The leader of the research team should authorise any release of the results on the Internet. Releasing information in this way may well compromise intellectual property rights, so there should be a suitable mechanism to monitor information placed on the web.

6.2 Authorship

- Authorship of papers should include those individuals who have made a major contribution to the work and who are familiar with the entire contents of the paper. Authors should have participated sufficiently in the research to take public responsibility for the content. The MRC subscribes to the guidance of the International Committee of Medical Journal Editors,[11] to which researchers should refer.

- Other contributions to the work should be acknowledged formally, as should financial support from sponsors. Authors are responsible for obtaining written permission from persons acknowledged by name.

6.3 Methods of publication

- Work should normally be published as a coherent entity rather than a series of small parts, unless there is a legitimate need to demonstrate first discovery by publishing preliminary data.

- Quality rather than quantity is paramount; the proliferation of multiauthor papers to increase quantity should be discouraged.

- Authors must not publish the same data in different journals.

6.4 Correction of errors and retraction of published findings

- If an error is found that degrades the worth of published findings, the principal author must immediately discuss the matter with the research leader, with a view to notifying co-authors and publishing a correction as soon as possible setting out the basis of the reservations.

- Where the findings are found to be in serious doubt, a retraction should be published speedily.

- Where fraud is suspected, the procedure set out in the *MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct*[1] should be followed.

7 Applying and exploiting the results

The MRC's mission can only be fulfilled if the results of research are communicated effectively. The MRC therefore expects those it supports to play their part in disseminating balanced information on scientific advances and their potential implications for society to the health professionals and policy makers who will be involved in applying them, and to the wider public.

7.1 Commercial exploitation

Since part of the MRC's mission is to improve quality of life and economic competitiveness, MRC-funded researchers are expected to maximise the prospects of research being taken into practice through the commercial route by protecting intellectual property rights (IPR).

- Intellectual property can only be protected adequately if researchers keep thorough, accurate, and contemporaneous research records.
- Researchers who collaborate with industry should take special care to keep detailed records of their research.
- IPR should be considered before data are submitted for publication or presented at meetings.
- All intellectual property, know-how, reagents, or materials generated by MRC employees while on MRC premises, or in connection with MRC research activities, is the property of the MRC. This is usually also the case for visiting workers who use MRC research facilities.
- Data placed on the web are considered to be in the public domain and so cannot be protected.
- Material transfer agreements (MTAs) and confidentiality agreements are important for protecting resources that may potentially have great value. MTAs are agreements between sender (eg, MRC) and recipient organisations regarding provision of research materials; they set out the terms on which the provider is prepared to release its material to the recipient. Confidentiality agreements recognise the need for tentative research and/or development partners to share proprietary research findings and/or commercial technologies before making formal commitment to a partnership; they therefore bind and protect the parties by limiting use of exchanged information to the discussions in hand. Researchers should generally seek expert guidance before entering into these agreements.

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