



The Association of Medical Research Charities

Guidelines on Good Research Practice

The Association of Medical Research Charities (AMRC) expects the highest standards of integrity to be adhered to by the researchers who are funded by medical research charities.

To facilitate this process, AMRC has drawn up these 'Guidelines on Good Research Practice'. The guidelines build on those already published by The Wellcome Trust adding issues of particular concern to AMRC charities.

AMRC member charities fund a wide range of types of research including basic, applied and disease specific. They provide funds in a variety of different ways from small pump-priming grants to substantial level of funds intended for programmes of research. The majority of charity funded research is carried out in institutions where the charity itself is not the employer and grant giving charities look to the host institution to implement good research practice.

In addition to research institutions in receipt of AMRC charity grants, AMRC would expect the following groups to be made aware of the guidelines:

- Researchers and others who apply for or receive funding from an AMRC member charity.
- Trustees and staff of AMRC member charities.
- Research and advisory committees of AMRC member charities and other's who may be involved in the peer review process (such as grant administrators/research managers and referees).

AMRC has recommended to its member charities, that with effect from 1 January 2003, it should be a condition of their grants that host institutions in the UK and the Republic of Ireland have in place their own published standards of good research practice which include formal written procedures for the investigation of allegations of research misconduct. The AMRC recommends that in addition to the issues outlined in this document, institutions should follow the Wellcome Trust '*Statement on the Handling of Allegations of Research Misconduct* and the principles set out in the AMRC statement on Scientific Integrity 1997.

AMRC recommends that member charities obtain written evidence of an institutions' own published standards of good research practice and written evidence of procedures for the investigation of allegations of research misconduct. These documents could be obtained as part of the grant application process.

1 Introduction

The AMRC has over 100 member charities who together contribute more than £600 million to medical research every year in the UK. They are a major source of funding for research in universities for all areas of medicine.

Medical research charities can only fund research that falls within their charitable objects. These objects may focus on a particular disease or condition, a range of diseases or more widely on improving human health through education and research.

Charity law imposes certain obligations and restrictions on the use of charitable funds for research, for example a requirement to disseminate research findings and a proscription on funding research for the purpose of commercial or private gain. Institutions should be aware of these conditions when in receipt of charitable funding.

The AMRC cannot be prescriptive about individual approaches taken by researchers to solving particular research problems. However, the AMRC expects institutions to ensure that an adequate structure exists to promote and promulgate good research practice, emphasizing integrity and rigour in research, and to create a culture in which the following general principles can be understood and observed.

Researchers are also reminded that they are accountable to the charity that supports them and should ensure that any charitable funds received are used for the purpose agreed.

The AMRC also expects that host institutions have in place formal written procedures for the handling of allegations of research misconduct. Useful models for such procedures can be found in The Wellcome Trust '*Statement on the Handling of Allegations of Research Misconduct*' and MRC's '*Policy and Procedure for Inquiring into Allegations of Research Misconduct*'. AMRC believe it is essential that both 'whistleblowers' and the 'accused' are adequately protected when research misconduct is investigated.

2 Application Process

The AMRC expects that the principles of these guidelines on Good Research Practice to apply both to the grant application process and the subsequent research. In addition researchers applying for funding from an AMRC member should:

- not make the same application to several charities/medical research funders at the same time unless each charity/medical research funder is made aware.

AMRC has set out guidelines for the use and practice of peer review by charities. This ensures that the medical research charities are aware of their responsibilities as funders and only fund the highest quality research.

3 Integrity

Researchers should be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research work, including experimental design, generating and analysing data, applying for funding, publishing results, and acknowledging the direct and indirect contribution of colleagues, collaborators and others.

Researchers are also accountable to society, their profession, the institutes where the research is taking place, the staff and students involved and, in particular, the charity that is funding the research. Researchers are expected to understand and apply the following principles:

- Plagiarism, deception or the fabrication or falsification of results should be regarded as a serious disciplinary offence.
- Researchers are encouraged to report cases of suspected misconduct and to do so in a responsible and appropriate manner.
- Researchers should declare and manage any real or potential conflicts of interest, both financial and professional. These might include:
 - Where the researchers have an existing or potential financial interest in the outcome of the research;
 - Where there is a private or private practice benefit significantly dependent upon the outcome of the research;
 - Where the researcher's professional or personal gain arising from the research may be more than might be usual for research.

4 Openness

While recognising the need for scientists to protect their own research interests, the AMRC encourages researchers to be as open as possible in discussing their work with other scientists and with the public. The aim in disseminating charity funded research is to increase knowledge and understanding: its purpose should not be primarily to seek publicity for the researcher, the research institution or the funder.

Once results have been published, AMRC expects researchers to make available relevant data and materials to other researchers, on request, provided that this is consistent with any ethics approvals and consents, which cover the data and materials and any intellectual property rights in them.

The AMRC recognises that publication of the results of research may need to be delayed for a reasonable period pending protection of intellectual property arising from the research. However, any such periods of delay in publication should be kept to a minimum.

Researchers should be especially careful when discussing work that is not complete or has not been published, particularly if it has not undergone peer review.

Any research institute which holds a certificate under the Animals (Scientific Procedures) Act 1986 and carries out research using animals should have a policy statement on the ethical use of animals available to funding bodies or to others on request.

5 Guidance from professional bodies

Where available, AMRC expects researchers to observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies.

All researchers should be aware of the legal requirements, which regulates their work.

6 Leadership and cooperation

Heads of institutions and their senior colleagues should ensure that a research climate of mutual cooperation is created in which all members of a research team are encouraged to develop their skills and in which the open exchange of ideas is fostered.

7 Supervision

Institutions should ensure that appropriate direction of research and supervision of researchers is provided. Training in supervisory skills should be provided where appropriate.

A code of practice on the responsibilities of supervisors should be available indicating, for example, the frequency of contact, responsibilities regarding scrutiny of primary data, and the broader development needs of research trainees.

The need should be stressed for supervisors to supervise all stages of the research process, including outlining or drawing up a hypothesis, preparing applications for funding, protocol design, data recording and data analysis.

8 Training

Institutions should have in place systems which allow students and new researchers to understand and adopt best practice as quickly as possible.

All researchers should undertake appropriate training, for example, in

- research design
- regulatory and ethics approvals and consents
- equipment use
- confidentiality
- data management
- record keeping
- data protection
- Home Office training to gain licences when using animals in medical research
- management of intellectual property
- involvement of patients and consumers
- NHS research governance requirements
- conduct of clinical trials

9 Primary data/samples/equipment

There should be clarity at the outset of the research programme as to the ownership and use of, where relevant:

- data and samples used or created in the course of the research; and
- the results of the research
- patient questionnaires
- equipment paid for by the charity

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 situations where questions are subsequently asked about either the conduct of the research or the results obtained.

Materials obtained for use in experiments, such as cell cultures and other biological samples, should be fully documented and validated. Researchers should be able to confirm the source and, if necessary, verify the identity of the sample.

Data generated in the course of research should be kept securely in paper or electronic format, as appropriate. AMRC considers a minimum of ten years to be an appropriate period. However, 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).

Researchers should report any changes in the direction of charity funded research to the charity and to any other relevant body. Best practice would be to discuss any change in direction of the research with the charity prior to its implementation.

10 Ethical practice

10.1 Research involving human participants

Approval from the appropriate research ethics committees is required for all research funded by AMRC member charities that involves human participants or human biological samples.

In most cases AMRC member charities expect the relevant regulatory approval to be in place before funding is allocated to a researcher. AMRC reminds researchers that where appropriate the following bodies should be contacted and/or consulted:

- Local Research Ethics committees (LREC)
- Multi-centre Research Ethics committees (MREC)
- The host institutions' own Research Ethics Committee and those of collaborators.

AMRC also reminds researchers of the importance of regulatory approval from bodies such as:

- Human Fertilisation and Embryology Authority
- Gene Therapy Advisory Committee

AMRC recommends that researchers also contact:

- any relevant professional or scientific body

and in some cases it may be appropriate to seek the views of relevant patient groups.

Researchers should ensure the confidentiality of personal information relating to the participants in research, and that the research fulfils any legal requirements such as those of the Data Protection Act 1998.

10.2 Research Governance Framework

AMRC is supportive of the aims set out in the Research Governance Framework and commends the work undertaken by the Department of Health and others in working towards high standards of clinical research governance in the NHS. Researchers should ensure that their research is supportive of the NHS Research Governance Framework.

10.2 Research involving animals

AMRC requires that research involving animals should have approval of the following (through the appropriate bodies)

- Ethical Review Process
- Home Office licences for the institution, the investigator and the project.

Researchers should consider, at an early stage in the design of any research involving animals, the opportunities for reduction, replacement and refinement of animal involvement (the three Rs). Researchers should refer to AMRC's guidelines on '*Promoting good practice in research involving animals*'.

The aim should be that experimental design for animal studies should be of the same quality as for clinical trials.

10.3 Research Using Stem Cells

Stem cells are undifferentiated cells that have the potential to give rise to a number of different cell and tissue types. *Human embryonic stem (HES)* cells are of particular importance to research but their use has often provoked controversy

In 2002 a House of Lords Select Committee was appointed to investigate the use of stem cells in research. It recommended that a stem cells bank be set up to curate and store stem cell lines for the purposes of future research. Research using HES cell lines is not subject to direct regulation by the Human Fertilisation and Embryology Authority (HFEA). However, the select committee recommended that a steering committee be set up to oversee research in this area.

AMRC expects that researchers using HES cells will abide by the recommendations of the steering committee. Accordingly, researchers are expected:

- To use HES cell lines only for important research purposes, reflecting the priorities of the HFEA; including:
 - *research which increases knowledge about the development of embryos or has the long term goal of helping to increase knowledge about serious diseases and their treatment (as in the 2001 HFEA Regulations)*
 - *basic cell research which underpins these aims (as recommended in the House of Lords Report 2002)*
 - *development of cell based therapies for clinical trials in respect of serious human diseases*
- To preferentially seek to access HES cell lines from the UK stem cell bank and to inform the steering committee if using HES cell lines from an alternative (e.g. international source).
- If using internationally sourced HES cells, to provide evidence that the cells have been obtained in a manner which is in accordance with ethical regulations and with the informed consent of the donor (this approval will already have been obtained for cells held in the UK stem cell bank, as depositing cells in the bank must be done in accordance with HFEA regulations, 2001).
- To negotiate appropriate Material Use Licenses with the depositor, necessary for the release of cell lines by the stem cell bank.

For further information on this area, researchers should refer to the MRC's "*Code of practice for the use of human stem cell lines*"; available at:

<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003132>

11 Dissemination/publication practice

AMRC understands that researchers must have academic freedom and charities would not wish to discourage publication or dissemination of research or research findings.

AMRC encourages the publication of and dissemination of high quality research but believes that researchers must do this responsibly and with an awareness of the consequences of dissemination in the wider media.

AMRC recommends that every effort should be made to inform the funding charity/charities of any potential publication or dissemination of the research findings. This will enable the charity in question to have adequate time and accurate information to plan their own public relations. This can be especially important to fund-raising charities.

Charity supported researchers should take into account the following guidance when publishing or disseminating their research or research findings including any plans to publish or publicise research at conferences or on web sites:

- The charity should be notified in advance when the research might be published, publicised or disseminated.
- Researchers should make every effort to make sure research is peer reviewed prior to it being published, publicised or disseminated. If research is placed in the public domain before peer review has been undertaken the researcher and research institution must make this clear in any publicity.
- All funding sources must be acknowledged in any publication or publicity.
- Results of research should be published in an appropriate form, usually as papers in refereed journals.
- Anyone listed as an author on a paper should accept responsibility for ensuring that he/she is familiar with the contents of the paper and can identify his/her contribution to it. The practice of honorary authorship is unacceptable.
- The contributions of formal collaborators and all others who directly assist or indirectly support the research should be properly acknowledged.
- An example of good publication practice can be found in the Committee on Publication Ethics guidelines '*Good Publication Practice*'.

12 Patient aspects/consumer involvement

Researchers should consider and be aware of the active involvement of patients and consumer groups in research and the dissemination of research findings. It is important that researchers consider the impact any publication of research findings may have on patients with the condition, those involved in their care, those involved in the research and consumer groups.

Further details about user involvement can be found in the NHS document '*Research: What's in it for consumers?*' and the MRC '*Guidelines for Good Clinical Practice in Clinical Trials*' 1998.

13 Intellectual Property

Researchers must inform charities of any intellectual property rights that may arise or arise from research they have funded. Although it is usual for the host institution to own the intellectual property arising from the research the charity has funded it is important to remember that intellectual property rights could not have been generated without the financial support for research activity provided by the charity.

AMRC members fund research for public benefit and not for commercial or private gain. The public benefit may arise from education, i.e. the gain of knowledge that is placed in the public domain, or improvement in treatment or care of patients or in curing or preventing disease. A

charity cannot support a piece of research solely for the purpose of commercial gain although commercial benefit may accrue to the charity from the research.

Further details of Trustees responsibility towards intellectual property rights can be found in the AMRC *'Charities and Medical Research-Part 2 Management of Commercially Exploitable Intellectual Property'*.

References

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Other sources of information

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