Section 2
Guidelines and standards

These guidelines and standards outline how the principles above should be applied within MRC research units and institutes and clarify the MRC's expectations for MRC-funded research within universities, medical schools, hospitals and other research organisations.

They apply to everyone involved in MRC-funded research including researchers, research support staff, students, research managers and administrators.

A Planning and conducting MRC-funded research

A.1 Those planning and delivering MRC-funded research should have the necessary expertise, professional skills and experience to deliver the project proposed. This may include seeking specialist advice or securing access to expertise through collaboration. Plans should include an assessment of all resources needed (including staff, space, funding, facilities, biological resources and clinical support) to ensure the study is viable within the available means and the efficient and proper use of all resources. This position should be reviewed as the project progresses. Researchers supported by the MRC should consider at an early stage of the design of the project how they will adhere to the principles and standards of *Good Research Practice* over the course of their research and aim to anticipate any issues or challenges that might arise.

A.2 The rationale for the study and any subsequent modifications must be clearly documented within a well maintained system, for example in project proposals, contracts, protocol documents, laboratory notebooks or as electronic records. All projects must be documented clearly, systematically and in a timely manner, including clear outcomes and end points, plans for statistical analysis, any ethical and regulatory approvals and any subsequent amendments. Key records or documents should be held in an accessible form. Any changes should be validated and recorded with appropriate version control by the researcher responsible, to establish the provenance of the study and protect intellectual property.

A.3 MRC-funded research must adhere to current ethical standards, safety practices, relevant legal requirements, local organisational policies and other guidelines. Researchers should ensure they are aware of, and keep up to date with, all the regulatory, ethical and governance requirements that may apply to their area of research and are working with the teams and individuals within their organisations who have a corporate responsibility to ensure that these requirements are adhered to within the organisations. All appropriate licences and permissions must be in place before the research starts and updated as necessary if plans change. The expectations and requirements of professional codes of conduct and standards, including arrangements for managing consent and information governance should be addressed in the planning and conduct of the study (see section D below).

A.4 For all research involving people as participants, their tissues or data, the relevant principles of Good Clinical Practice (GCP), an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects, should be followed (13). Where practicable, consent that is freely given and informed should be sought from all competent participants. Guidance on writing participant information is available from the National Research Ethics Service (NRES)(14); this includes guidance for research that involves adults who lack capacity to give consent or children (15). Consent discussions should include how feedback on any health related finding will be handled, what withdrawal from a study will mean in practice and that this can occur at any time and for any reason up to the point of data analysis or up to the point of submission for publication. In line with the MRC's policy on data and tissue

sharing, participants should also be made aware of potential reuse in future research and the arrangements for consent.

A.6 Responsibilities for overseeing the scientific and ethical conduct of the study must be identified, allocated and agreed as the scientific plans are put into practice. This is especially important in projects involving patients, volunteers or confidential or identifiable data, tissue, biological samples and animals and in other complex, collaborative programmes.

A.7 Research organisations should have appropriate research governance systems, in which roles are allocated to meet corporate and individual project responsibilities, and are accepted and carried out within a sound research and project management framework. This may involve the identification of sponsors, appropriate and proportionate quality, risk management and monitoring systems, or the use of preferred project management processes or tools. When considering proportionate risks important aspects to consider include the impact on research delivery, supporting creativity, the credibility and robustness of results and the risks involved in methods used in studies involving human participants.

A.8 The proper use and maintenance of equipment and systems is an important element of the research process. Appropriate procedures should be in place and responsibilities assigned to ensure training and support for use, regular servicing and calibration of equipment by trained staff, appropriate records of calibration, servicing, faults, breakdowns and misuse.

A.9 Where possible, and most often for studies involving patients and volunteers, researchers should engage with service-users, carers, representative groups and other stakeholders and beneficiaries in the design, conduct, analysis and reporting of research. Advisory bodies which promote active public and patient involvement should be consulted as appropriate (20)(21).

Related links

(1) RCUK policy and code of conduct on the governance of good research conduct, Integrity, Clarity and Good Management (2013): http://www.rcuk.ac.uk/RCUK-prod/assets/documents/reviews/grc/RCUKPolicyandGuidelinesonGovernanceofGoodResearchPracticeFebruary2013.pdf

(2) MRC policy on health department research governance frameworks: http://www.mrc.ac.uk/research/research-policy-ethics/clinical-research-governance/

(4) Universities UK Concordat to Support Research Integrity: http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf

(5) UK Research Integrity Office, Code of practice for research: Promoting good practice and preventing misconduct (2009) and Recommended Checklist for Researchers: http://www.ukrio.org/publications/code-of-practice-for-research/

(11) RCUK and MRC terms and conditions for grants: http://www.rcuk.ac.uk/funding/grantstcs/

(12) RCUK statement of expectation on economic and societal impact: http://www.rcuk.ac.uk/Publications/archive/StatementofExpectationon/

(13) Good Clinical Practice principles: www.ichgcp.net

(14) HRA guidance on consent: http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/

(15) MRC ethics series; Personal information in medical research, Medical research involving adults who lack capacity to consent, Medical research involving children: http://www.mrc.ac.uk/research/research-policy-ethics/

(16) MRC Regulatory Support Centre resources and tool kits: http://www.mrc.ac.uk/research/facilities/regulatory-support-centre/

(17) MRC policy on research data sharing and preservation: http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/

(18) UK research funders vision for human tissue resources: http://www.ukcrc.org/research-infrastructure/experimental-medicine/funders-vision-for-human-tissue-resources/

(19) RCUK Concordat and guidance on engaging the public with research: http://www.rcuk.ac.uk/pe/Concordat/

(20) NIHR guidance on patient and public awareness: http://www.nihr.ac.uk/get-involved/

(21) INVOLVE: Promoting public involvement in research: www.invo.org.uk/resource-centre

(22) NIHR Clinical Research Network: http://www.crn.nihr.ac.uk/

B Data: management, integrity, retention and preservation

B.1 MRC-funded research covers a broad spectrum, including fundamental lab-based science, population health science, patient-based studies and clinical trials. All research data generated through MRC-funded research must be managed and curated effectively throughout its lifecycle, including archiving, to ensure integrity, security and quality and where possible to support new research and research data sharing (17) (23) to maximise the benefit and impact of MRC research funding. Records should be kept to enable understanding of what was done, how and why, and which allow the work to be assessed retrospectively and repeated if necessary.

B.2 The principles, standards and technical processes for data management, retention and preservation will be determined by the area of science, for instance the needs of fundamental studies may differ from population-based and clinical studies. Processes should be supported by appropriate data standards addressing confidentiality and information security, monitoring and quality assurance, data recovery and data management reviews where suitable.

B.3 Research data generated in the course of MRC-funded research must be retained in an appropriate format in line with agreed retention periods (see box 1 below). Related material should also be retained to ensure accessibility, integrity, the application of new analytical tools or statistical techniques, and to enable new research where possible (see box 1 below).

Box 1: Retaining research data

Types of research data

Primary/raw data include any information, images, observations, questionnaires, products, devices, procedures and any other data sources that are generated, recorded or used during the project.

Related material includes approvals, information on the consent process (including signed consent forms), meta-data, information relating to analysis and methodology, quality assurance records that demonstrate the validity of the data and/or adherence to experimental protocols, calibration data, collaborative agreements, intellectual property ownership, management and agreements and other relevant correspondence.

Confidential identifiable data comprise any information that relates to an individual (either living or dead) from which that individual can be identified.

The main record refers to the record where the research data are primarily recorded (for example, in electronic or hard copy laboratory notebooks, clinical trial master files).

Requirements

- All research data must be recorded and retained securely (for example, in electronic or hard copy laboratory notebooks) in a form that is original, legible, attributable and contemporaneous.
- Normally, specimens and samples should be retained within the research establishment that utilised them in line with relevant legislation, approvals and governance arrangements. Any transfer or disposal should be documented.
- Questionnaires, digital/audiotapes, etc should be retained in their original form within the research establishment that generated them.
- Where research data relating to a project are held in different formats (for example, completed questionnaires, machine readings, images and scans), these must be cross-referenced and recorded in the main record.
- The main record should be updated as soon as possible after data are collected; where the dates of collection and recording are different, this should be recorded.
- The main record should be approved by a supervisor to evidence that records are complete and accurate. Queries should be discussed as soon as possible and any changes resulting should be signed-off by the relevant parties.
- Information relating to participant consent should be held securely and subject to the same retention criteria as the primary/raw data.

Retention periods

Retention periods for primary/raw data and related material should be considered at the outset and should reflect any legal and regulatory requirements and, where possible, the aim to support new research.

The MRC's expectations for research data retention are:

- Basic research
  - If no restrictions apply, deposit primary/raw data and related material in an appropriate repository and/or publication should be considered.
  - Research data and related material should be retained for a minimum of 10 years after the study has been completed.
- Population health and clinical studies
  - The retention period for primary/raw data and related material from population health or clinical studies will be informed by the relevant regulatory framework, the legal requirements outlined in guidance from the MHRA and any additional requirements identified by ethics committees or professional codes.
  - For clinical research undertaken in MRC research units and institutes, the MRC expects research data relating to such studies to be retained for 20 years after the study has been completed to allow an appropriate follow-up period.
  - Studies which propose retention periods beyond 20 years must include valid justification, for example, research data relating to longitudinal studies will often be retained indefinitely and archived and managed accordingly.

Where complete retention of all research data is not appropriate, the data must be validated using quality assurance procedures and the justification carefully assessed before any data are destroyed. Further guidance relating to retention periods can be found in the Clinical Trials and Data and Tissues tool kits.

Research data relating to studies which directly inform national policymaking should be considered for permanent preservation or deposit in an archive or repository: discussions may need to involve staff across the MRC, including experts in data management and research governance. In some cases the potential

impact on policy may be a clear aim of the study, while in others the significance may only come to light later. It may therefore be necessary to consider the impact of the study at several stages during its life-cycle, particularly for studies which have long-term goals and which may be running for many years.

Retention, storage and archiving

- All primary/raw data and related materials retained, stored or archived should be recorded and held securely, in such a way as to allow them to be understood and used by others in future. This would include information about regulatory and ethical requirements relating to access and use.
- Research data held electronically should be backed up regularly and duplicate copies held in a secure and accessible format where possible.
- The digital continuity and future accessibility of electronic records and data should be considered.

B.4 Research data (including images) should be recorded and retained. Retention periods should be informed by data management and quality assurance needs. Where primary/raw data are subsequently enhanced, original and enhanced data should be stored together. It is important to avoid the over-enhancement or over-interpretation of data and images.

B.5 It is essential to manage confidential identifiable data appropriately, including data associated with tissue and biological samples. A number of tool kits have been developed to provide a guide to the regulatory environment including the *MRC Data and Tissues tool kit* (24) which outlines the requirements for use of confidential identifiable data and human tissue samples in healthcare research. The tool kit route maps are aimed at guiding researchers through the planning and approvals process and provide practical help on legislative and good practice requirements as well as a summary of MRC policies in this area. Publication of any research data, including in Masters/Doctoral theses or in an accessible data repository, does not negate the need to retain primary/raw data.

B.6 Local procedures (for example, Standard Operating Procedures, protocols, etc) for all routine methods to be replicated across a study, together with associated risk assessments, should be documented systematically, in plain English and ideally in a standard format to ensure clarity, consistency and accuracy. Where there is more than one approved technique for any given procedure within the organisation, clear records should be kept on which were used. Where procedures change, they should be version controlled and the current version should be available and readily accessible to all staff, students and visiting workers.

B.7 Protocols for the use, calibration and maintenance of equipment, together with associated risk assessments, must be clearly documented to ensure optimal performance and research data quality. Where protocols change they should be version controlled and the current version should be available and readily accessible. Instructions for the safe shutdown of equipment in case of emergency should be readily accessible. Such quality assurance measures as outlined in B.6 and B.7 help demonstrate the robustness and validity of research data.

B.8 To maximise public benefit the MRC supports open access (27) to the published outputs of research in a timely manner as well as initiatives that aim to extend access to research data and resources generated in the course of MRC-funded work. These may include the preservation and sharing of datasets and other relevant materials in line with the MRC's policy on research data sharing (17). Where it is possible to share data and materials, guidance must be provided to ensure they are used appropriately, with proper regard for issues relating to consent, confidentiality and in accordance with any relevant data security guidelines, including guidance on encryption and data management, and other relevant conditions.

B.9 There should be clarity on the ownership and custodianship of research data, samples and related material used or created in the course of the research. Agreements should be used to clarify

responsibilities, arrangements for access to data and managing permissions, including sharing with collaborators or with researchers who move away from the original organisation. Agreements should be developed at an early stage and should take account of requirements imposed by the research funder in their terms and conditions. Agreements might outline the responsibilities of steering groups, research investigators and team leaders in relation to these issues. Where personal data and/or biological samples are involved, the terms of the consent must be taken into account. Model agreements, such as those developed by UKCRC working groups, should be considered where relevant (29).

B.10 Where an MRC unit is due to close or where programmes end and programme leaders or principal investigators transfer or retire, arrangements must be made in advance to support the retention and management of samples and data. This may include the transfer of custodianship to another individual within the unit or to another organisation and arrangements should detail provisions for access and eventual destruction. Where relevant the Data Controller and/or the Designated Individual of the new organisation should be notified.

Further guidance on MRC policy on research data sharing, preservation and management can be found on the MRC website.

Related links

(11) RCUK and MRC terms and conditions for grants: http://www.rcuk.ac.uk/funding/grantstcs/

(16) MRC Regulatory Support Centre resources and tool kits: http://www.mrc.ac.uk/research/facilities/regulatory-support-centre/

(17) MRC policy on research data sharing and preservation: http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/

(23) MRC Guidance on data sharing requirements for population and patient studies http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/population-patient-studies/

(24) MRC Data and Tissues tool kit: www.dt-toolkit.ac.uk

(25) UK Clinical Trials tool kit: www.ct-toolkit.ac.uk

(26) MRC Information Security Policy: www.mrc.ac.uk

(27) MRC policy on open access publishing: http://www.mrc.ac.uk/research/research-policy-ethics/open-access-policy/

(28) Europe PubMedCentral: http://europepmc.org/

(29) UK Clinical Research Collaboration Model Agreements: http://www.ukcrc.org/regulation-governance/model-agreements/

C Collaborative working

C.1 MRC-funded research often involves collaboration, which can range in scale from simple discussions through to significant long-term partnerships. In some cases collaborations can raise significant risks and challenges for research governance. Discussion, and where necessary written agreements, should be used to clarify and agree key aspects, including responsibilities, common approaches or standards and procedures. Differences in practice or expectations should be identified and if necessary resolved. This is especially important where the work involves researchers from different disciplines, organisations and/or countries. Agreements must be drawn up and signed by properly authorised signatories within the research organisation and representatives of the collaborating organisation and finalised prior to the commencement of the work.

C.2 Most collaborations will usually require some of the following to be addressed during the course of the research. Formal collaboration agreements may include:

- Scope, duration and aims of the proposed project.
- Finance and in-kind resource commitments.
- Key tasks and responsibilities of the partners (including sponsorship arrangements where appropriate).
- Project management arrangements, including lines of accountability and communication.
- Training requirements and responsibilities.
- Health and safety arrangements for shared or seconded staff.
- Research governance standards and ethical and regulatory arrangements including approvals, confidentiality and use of animals.
- Publication and authorship.
- Ownership, custodianship, transfer and arrangement for the future use of research data and samples (including return or disposal).
- Arrangements for handling intellectual property (see H.4).
- Specific requirements for information governance and information security, including record keeping, data management, handling or transfer.
- Financial/resource contributions and liabilities/indemnity.
- Arrangements for reporting and handling allegations of research misconduct.

C.3 Agreements to support clinical research collaborations which involve the pharmaceutical and biotechnology industries, academia and NHS organisations across the UK should address issues relating to allocation of responsibilities, rights and liabilities. Examples of template agreements which may be used to support bespoke agreements include the *NIHR model Industry Collaborative Research Agreement* (30) and the UKCRC Academic Sponsor/NHS trust agreement.

C.4 Agreements involving international partners, or where work will be undertaken outside the UK and where different legislative or ethical requirements apply, require particularly careful negotiation. The guidance produced by international organisations, such as the European Science Foundation (31) and the OECD Global Science Forum (32), and statements developed by the research community, such as the *Singapore Statement on Research Integrity* (33) identify some of the key issues to consider.

Related links

(1) RCUK policy and code of conduct on the governance of good research conduct, Integrity, Clarity and Good Management (2013): http://www.rcuk.ac.uk/RCUK-prod/assets/documents/reviews/grc/RCUKPolicyandGuidelinesonGovernanceofGoodResearchPracticeFebruary2013.pdf

(4) Universities UK Concordat to Support Research Integrity: http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf

(5) UK Research Integrity Office, Code of practice for research: Promoting good practice and preventing misconduct (2009) and Recommended Checklist for Researchers: http://www.ukrio.org/publications/code-of-practice-for-research/

(30) NIHR model Industrial Collaborative Research Agreement (mICRA): http://www.nihr.ac.uk/policy-and-standards/standard-research-agreements.htm

(31) The European Science Foundation Code of Conduct for Research Integrity (2011): http://www.esf.org/coordinating-research/mo-fora/research-integrity.html

(32) OECD Global Science Forum, Investigating Research Misconduct Allegations in International Collaborative Research Projects: A PRACTICAL GUIDE (2009): http://www.oecd.org/science/sci-tech/researchintegritypreventingmisconductanddealingwithallegations.htm

(33) Singapore Statement on Research Integrity, developed following the 2nd World Conference on Research Integrity: www.singaporestatement.org

D Codes of conduct, ethics and professional standards

D.1 MRC-funded researchers must be aware of, and adhere to, all legal requirements and relevant codes of conduct required by their employer, place of work and any professional bodies to which they, or members of their research teams belong (34). In some areas of research, for example, for research involving human participants, corporate responsibility is assigned by the research organisation as employers, and in some cases sponsors, to specific individuals to act as health and safety officers, research governance leads, designated individuals on Human Tissue Authority licences, etc. These individuals will work closely with research teams within the organisation and have a responsibility to develop systems that provide accountability that the requirements placed on the employer are being met and to demonstrate that the organisation meets the highest legal and ethical standards.

The MRC's code of conduct for employees is available on the RCUK SSC Knowledgebase alongside other policies which apply when working within an MRC unit or institute.

D.2 All MRC-funded research involving human participants, human material, confidential identifiable information or the use of animals or regulated materials must address and comply with all necessary legal and ethical requirements and standards, including governance arrangements outlined in MRC policies and other relevant guidelines (34)(35)(36). The expectations and requirements of professional codes of conduct, standards and organisational policies should be addressed in the planning, resourcing and conduct of the study and all appropriate ethical, regulatory and NHS approvals must be in place before any research commences.

The MRC ethics series outlines relevant policies and requirements for specific areas, activities and research settings.

MRC research units/institutes are required to nominate a Research Governance representative to lead on the implementation of appropriate systems within the unit.

D.3 MRC-funded research involving international partners, or work undertaken outside the UK, must comply with all applicable legal and regulatory requirements. Research involving human participants should have ethical approval both in the UK and the country (or countries) where the work is being undertaken. Further information on ethical reviews in the UK can be found in the MRC Data and Tissues tool kit.

D.4 Specific requirements have been developed to support MRC-funded research under the Research Governance Frameworks of the UK Health Departments. The requirements focus mainly on sponsorship and employer's responsibilities and apply differently to MRC-funded research undertaken within MRC units/institutes and other research organisations; they are consistent with the MRC's policy on sponsorship under the UK Clinical Trials Regulations 2004 (37).

D.5 Specific requirements have been developed to support MRC-funded research under the UK Clinical Trials Regulations 2004. The requirements cover all clinical trials of investigational medicinal products supported by the MRC (38).

Further information and advice on meeting regulatory, ethical and governance requirements in research that involves human participants, their tissues or data is available from the MRC Regulatory Support Centre. www.mrc.ac.uk/regulatorysupportcentre

D.6. The MRC has high expectations for the design, conduct and reporting of medical research involving animals. Implementation of the 3Rs (replacement, refinement and reduction) is essential to meet ethical

standards and to obtain the best possible scientific results. The publication *Responsibility in the use of animals in bioscience research* (40) was coordinated by the NC3Rs (41) and outlines the expectations of the MRC and other UK research councils and charitable bodies which provide funding for research involving animals. Additional codes of practice and guidelines which relate to the use of animals in research issued by the MRC must also be adhered to.

Related links

(2) MRC policy on health department research governance frameworks: http://www.mrc.ac.uk/research/research-policy-ethics/clinical-research-governance/

(6) MRC ethics and research guidance: http://www.mrc.ac.uk/research/research-policy-ethics/

(8) MRC Code of Conduct for Employees: www.mrc.ac.uk

(24) MRC Data and Tissues tool kit: www.dt-toolkit.ac.uk

(34) For example: General Medical Council, Guidance on Good Practice in Research and related guidance on consent and confidentiality: www.gmc-uk.org/guidance/ethical_guidance/5992.asp

(35) For example: Department of Health Information Governance tool kit for research involving NHS patients and patient data: https://www.igt.hscic.gov.uk/

(36) For example: WHO research review ethics committee guidance on Ethical standards and procedures for research with human beings: www.who.int/ethics/research/en

(37) Clinical trials for medicines, UK legislation: www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials /Legislation/index.htm

(38) MRC policy on UK clinical trials regulations: http://www.mrc.ac.uk/research/research-policy-ethics/clinical-research-governance/clinical-trials-regulations/

(39) MRC policy on consent to take part in research, including research involving children, adults who lack capacity to consent and the use of personal information in research: http://www.mrc.ac.uk/research/research-policy-ethics/

(40) MRC policy and guidance on the use of animals in research, including guidance on the responsibility and use of animal in research: http://www.mrc.ac.uk/research/research-policy-ethics/use-of-animals/

(41) National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs): www.nc3rs.org.uk

E Research misuse

E.1 The risks of research outcomes being misused for harmful purposes, for example bioterrorism, must be considered throughout the whole life-cycle of an MRC-funded study. Mechanisms must be in place to ensure that a thorough risk assessment is undertaken, any risks of misuse are identified and actively managed, and that advice is available to research teams to take appropriate steps to minimise identified risks. The MRC position statement on bioterrorism and biomedical research provides advice on balancing benefit and risk in relation to potential misuse (9).

Related links

(9) MRC position statement on bioterrorism and biomedical research (2005): http://www.mrc.ac.uk/research/research-policy-ethics/bioterrorism/

F Safety, security and resilience

F.1 All of those involved in delivering MRC-funded research should ensure that all work for which they are responsible, including their own, fulfils all requirements of health and safety legislation and good practice. Appropriate training must be provided on safety measures for research which involves potentially hazardous or harmful materials and processes, and for research in risky settings or locations. In highly collaborative environments clear communication of appropriate procedures is essential.

F.2 The MRC Safety, Security and Resilience Team is responsible for central planning and policy development within MRC research units and institutes. They also support compliance assurance and provide advice and training to local teams and to MRC-staff. MRC policies, resources and training available within MRC research units and institutes can be found on the MRC's website (42).

F.3 Research organisations hosting MRC research are responsible for health and safety policy and procedures. Researchers undertaking activities within another research organisation must cooperate fully with the host on all health and safety matters.

F.4 Research organisations should have robust business continuity plans in place to ensure any interruptions to the operations of a project or programme are handled appropriately and that any impact on the research outcomes is minimised.

Related links

(42) MRC guidance on safety, security and resilience: http://www.mrc.ac.uk/skills-careers/working-for-mrc/safety-security-resilience/

G Reporting and disseminating research

G.1 Arrangements and responsibilities for the publication of results relating to MRC-funded research, including outline plans for public engagement activities and payment of open access fees, should be taken into account when planning the study and agreed at the outset. Arrangements should be made at an early stage and involve all investigators and should be revisited where roles and contributions change over the life cycle of the study; this is particularly important for collaborative and multidisciplinary projects.

G.2 Discussions may be needed to address authorship, including lead responsibility, authorisation for the content of papers and the intended place of publication and any pre-existing obligations. Arrangements should outline responsibilities for ensuring accuracy of methods, integrity of results, adequacy of internal peer review, appropriate protection of intellectual property, authorship and arrangements for the timely correction of any errors or retraction. For collaborative and multidisciplinary projects differences in publication practice across disciplines or institutions should be identified and addressed at an early stage.

G.3 Authorship should include all individuals who have made a substantial intellectual contribution and all authors are expected to take public responsibility for their contribution to the work. The MRC endorses the guidance of the Committee on Publication Ethics (43) and the International Committee of Medical Journal Editors (ICMJE) (44). The MRC endorses the ICMJE guidelines on authorship and contributorship; the practice of 'honorary authorship' is not acceptable. All contributions to the research must be clearly acknowledged and appropriate permissions sought for the use of the work of others. No person who fulfils the criteria for authorship should be excluded.

G.4 The contributions of funders should be clearly acknowledged and managed appropriately, particularly when using tools such as UK PubMedCentral (UKPMC)(28) and Researchfish (45).

G.5 When reporting research findings in publications, presenting at scientific meetings and engaging in debates in the media or in public, any relevant interests must be declared. This is to help others understand the factors that may have influenced the research team and would include any interests that might be considered by others, including the public, to be a conflict. Research findings that are likely to attract strong public or media interest should be drawn to the attention of the MRC and/or other research funders before publication.

G.6 The final results of MRC-funded research must be collated, summarised and subjected to quality assurance and, where appropriate, peer review. A conclusion should be drawn and the outcome confirmed by the research team. The MRC encourages the publication of all research findings, including findings that do not support the initial hypotheses to allow others to benefit from the work and to avoid unnecessary repetition.

G.7 The outcomes of MRC-funded research should normally be published as a coherent entity rather than as part of a series, unless there is a legitimate need to demonstrate first discovery by publishing preliminary data. Quality is paramount and the proliferation of papers to increase the quantity of publications is discouraged. Duplicate or redundant submission or publication is not acceptable as it may distort the evidence base upon which meta-analyses rely.

G.8 Agreed standards for reporting the outcomes of research in specific areas have been developed and should be observed. Standards endorsed and supported by the MRC include the CONSORT Statement (CONsolidated Standards of Reporting Trials) (46) and the ARRIVE guidelines (Animal Research: Reporting in-vivo experiments) (47).

Related links

(27) MRC policy on open access publishing: **http://www.mrc.ac.uk/research/research-policy-ethics/open-access-policy/**

(28) Europe PubMedCentral: **http://europepmc.org/**

(43) Committee on Publication Ethics, Code of conduct and related guidelines and resources: **publicationethics.org/resources/code-conduct**

(44) International Committee of Medical Journal Editors, guidance on ethical considerations and international standards: **www.icmje.org/index.html**

(45) Researchfish: **www.researchfish.com**

(46) CONSORT (CONsolidated Standards of Reporting Trials) Statement (2010): **www.consort-statement.org/consort-statement**

(47) ARRIVE: Animal Research: Reporting in-vivo experiments (2010): **www.nc3rs.org.uk/downloaddoc.asp?id=1206&page=1357&skin=0**

H Translation of research findings and management of intellectual property

H.1 MRC-funded researchers have a responsibility to ensure that any findings which have a potential impact on clinical practice, public policy or the development of new treatments or preventive interventions are actively disseminated to the relevant user community. Plans for translation of such findings should be put in place in order to ensure that potential benefits for health or healthcare are realised as quickly as possible.

H.2 The potential for MRC-funded research to generate intellectual property of value should be anticipated throughout the life cycle of the project. Researchers should ensure they are aware of the ownership and

arrangements for the management of intellectual property within their establishment. Steps should be taken to ensure that any results are effectively protected and any intellectual property generated is exploited.

H.3 All intellectual property, intellectual property rights, know-how, data, devices, reagents, or materials generated by MRC employees are normally the property of the MRC. This is usually also the case for visiting workers and students. Intellectual property generated within MRC units and institutes is managed by the MRC, in partnership with MRC Technology (49).

H.4 Arrangements for managing and handling intellectual property generated during a collaborative project, including additional conditions or requirements relating to the conduct of the project, should be clarified and agreed before any work commences. Transfer agreements and confidentiality agreements are important for protecting resources that may potentially have great value and should be considered. However, expert advice should be sought before entering into any such agreement; it is a requirement for MRC Technology to advise on all commercial contracts involving MRC units and institutes.

Related links

(11) RCUK and MRC terms and conditions for grants: http://www.rcuk.ac.uk/funding/grantstcs/

(48) RCUK knowledge exchange principles and position on intellectual property and asset management: http://www.rcuk.ac.uk/ke/policies/

(49) Medical Research Council Technology: www.mrctechnology.org

I Integrity in peer review

I.1 All researchers supported by the MRC are expected to participate in peer review, acting as reviewers for meetings, journals, grant applications and the ethical review of research proposals at a level appropriate to their experience and training. Peer review should be conducted to the highest standards and in line with the guidelines provided by the organisation seeking a review, including any obligation relating to confidentiality. Objectivity must be observed and any relevant conflicts of interest declared.

I.2 Those involved in peer review must not retain or copy any material under review or share it with others without express permission from the author and the organisation which requested the review. They must not make use of research designs or research findings from a proposal or paper under review without the express permission of the author(s) and should not allow others to do so.

I.3 While participating in peer review researchers are obliged to report appropriately, in confidence, any concerns they may have relating to research practice: such concerns may include plagiarism, fabrication, falsification, omission, ethical design or duplicate application.

Related links

(1) RCUK policy and code of conduct on the governance of good research conduct, Integrity, Clarity and Good Management (2013): http://www.rcuk.ac.uk/RCUK-prod/assets/documents/reviews/grc/RCUKPolicyandGuidelinesonGovernanceofGoodResearchPracticeFebruary2013.pdf

(5) UK Research Integrity Office, Code of practice for research: Promoting good practice and preventing misconduct (2009) and Recommended Checklist for Researchers: http://www.ukrio.org/publications/code-of-practice-for-research/

(43) Committee on Publication Ethics, Code of conduct and related guidelines and resources: publicationethics.org/resources/code-conduct

(44) International Committee of Medical Journal Editors, guidance on ethical considerations and international standards: www.icmje.org/index.html

J Conflicts of interest

J.1 The MRC recognises that conflicts of interest may arise, or appear to exist, at different levels of research endeavour from planning the research to disseminating and exploiting the results and in the associated peer review– and in many forms. Apart from financial interests, conflicts might, for example, be personal, academic, political or arise from the acceptance of gifts or hospitality.

J.2 The MRC expects procedures to be in place for identifying, declaring and addressing professional, private or commercial interests that might, or might be perceived to arise in relation to MRC-funded research. As much attention should be paid to perceived and potential conflicts of interest as to actual conflicts. All conflicts should be openly declared when reporting the outcomes of MRC-funded research at scientific meetings and conferences and in publications or when taking part in peer review.

J.3 The *MRC's Code of Conduct for employees* requires that any real, or perceived, conflicts must be discussed with the MRC unit director. Registers of declared interests and gifts and hospitality must be retained locally. Interests declared by members of the MRC's Council and decision-making bodies are routinely published (50).

Related links

(8) MRC Code of Conduct for Employees: www.mrc.ac.uk

(50) MRC Policy on Declarations of Interest: http://www.mrc.ac.uk/about/

K Allegations of research misconduct

K.1 The MRC takes allegations of misconduct in research very seriously and requires that allegations be investigated fully. Research misconduct is defined by the MRC and RCUK as follows:

- Fabrication.
- Falsification.
- Plagiarism.
- Misrepresentation.
- Mismanagement or inadequate preservation of data and/or related materials.
- Breach of duty of care.

These terms are defined in detail in the *RCUK Policy and Code of Conduct* and the process for investigating allegations in the *MRC Procedure for investigating allegations of misconduct in research* (51).

K.2 The MRC requires organisations receiving MRC funding to have appropriate processes for addressing allegations of misconduct. The process for reporting concerns and making formal allegations must be clear and accessible. Processes for investigating allegations must be thorough, fair, constructive, conclusive and timely.

The MRC procedure for investigating allegations of misconduct in research outlines the process which applies within MRC research units and institutes.

The MRC procedure also acts as a guide to the MRC's expectations as they relate to the requirements outlined by RCUK.

K.3 The MRC expects that wherever possible allegations of misconduct will be raised with the researcher's employer directly. However, where allegations relating to MRC-funded researchers, or to applications for funding, are reported to the MRC, the matter will be raised with the relevant research organisation(s), in confidence, at the earliest opportunity. The MRC reserves the right to take appropriate action after consultation with the research organisation.

K.4 As a research funder the MRC should be informed, in confidence, of any formal investigations of research misconduct relating to any individual funded by, or engaged with, the MRC, including those acting as a supervisor for an MRC postgraduate student or engaged with peer review activities, even where the work to which the allegation relates is not connected with an MRC-funded project. The MRC reserves the right to take appropriate action, after consultation with the research organisation, about any duties being performed for the MRC.

K.5 Where any investigation finds a distortion or inaccuracy in the published research record the institution should take all necessary steps to correct the public record.

K.6 Arrangements for handling allegations relating to research misconduct should be addressed explicitly in collaborative research agreements, particularly those involving international partners.

K.7 The MRC expects research organisations to be aware of the potential for fraud in relation to the conduct of research (for example duplicate applications for research funds for a project already funded) and have arrangements in place to address any such allegations.

Related links

(1) RCUK policy and code of conduct on the governance of good research conduct, Integrity, Clarity and Good Management (2013): http://www.rcuk.ac.uk/RCUK-prod/assets/documents/reviews/grc/RCUKPolicyandGuidelinesonGovernanceofGoodResearchPracticeFebruary2013.pdf

(51) MRC Procedure for investigating allegations of misconduct in research: http://www.mrc.ac.uk/research/research-policy-ethics/allegations-of-research-misconduct/

L Supporting training and skills

L.1 All research organisations in receipt of MRC funding are expected to foster an environment and culture where the open exchange of ideas is supported and where best practice and good conduct in research and publication is actively promoted at all levels of the organisation.

L.2 The MRC supports the *Concordat to Support the Career Development of Researchers* (10). All of those involved in MRC-funded research have a responsibility to develop and maintain the skills, competencies and understanding they need in their research, to develop their professional expertise and to assist others with their development.

L.3 Research leaders and research organisations are expected to provide direction and leadership, setting out clear lines of responsibility and accountability, for the organisation and management of research.

Resources, training and opportunities for development must be made available to deliver the design, management and governance of research, supervision and professional development of others to achieve the highest standards.

L.4 Systems should be in place to support students and new researchers in understanding and adopting good practice at an early stage in their research career and to support supervisors and research team leaders in understanding and discharging their responsibilities.

Related links

(10) The Concordat to support career development for researchers, an agreement between the funders and employers of research in the UK (2008): https://www.vitae.ac.uk/policy/concordat-to-support-the-career-development-of-researchers