

The MRC additional terms and conditions of funding supplement those of UKRI. These conditions set out operational, legislative and ethical requirements relating to medical research. The MRC reserves the right to vary these additional terms and conditions.

Research organisations and award holders¹ have absolute responsibility for ensuring all required licenses, approvals, permissions and consent are in place before any research is undertaken and that these are followed.

MRC reserves the right to audit at any time without prior notice:

- That required licenses, approvals, permissions and consent are in place, or were in place when the activity occurred.
- Compliance with the terms and conditions set out here.

AC1 Responsibilities of the Research Organisation: Clinicians

The research organisation is responsible for ensuring all clinicians supported by MRC funding are aware they are individually responsible for maintaining appropriate professional indemnity insurance. This should be with a professional defence organisation for any activities not covered by NHS indemnity arrangements or by additional provision made by the research organisation. MRC will not meet the costs of such cover.

The research organisation is responsible for ensuring any honorary clinical contracts required by clinical staff have been obtained prior to the start of the research.

The MRC expects the research organisations to abide by the 'UK clinical academic training in medicine and dentistry: principles and obligations' (mrc.ukri.org/documents/pdf/clinical-principles-and-obligations-report/).

AC2 Clinical Responsibilities

Clinical Fellowship holders (Clinical Research Training Fellowships, Clinician Scientist Awards or Senior Clinical Fellowships) may not work more than the time commitment for clinical duties stated in their proposal. For the majority, this will equate to up to 20% (on average over the lifetime of the grant) of their normal working hours, which they may choose to spend on NHS clinical sessions, teaching and demonstrating, or research activities beyond the scope of their fellowship. Exceptions are made for surgeons and fellows undertaking patient-oriented research, who may undertake up to 40% of their time on these duties. This is not in addition to the six hours per week all research staff supported full-time by an MRC grant or fellowship may undertake under RGC 8 of the Research Council Terms and Conditions of Research Council FEC Grants (www.ukri.org/funding/information-for-award-holders/grant-terms-and-conditions/).

AC3 Publicity for MRC-Funded Research

All research results and achievements should be communicated to the MRC Press Office (press.office@mrc.ukri.org) before publication.

¹ Award Holders are all MRC Grant Holders and recipients of MRC Unit and Institute funding (programme leaders)

Award holders must inform the MRC Press Office as soon as a paper presenting MRC-funded research is accepted for publication. The MRC reserves the right to lead on publicity when the MRC is the majority funder. The MRC Press Office must be notified at least 5 working days in advance of any publicity arising from MRC funding, and any press releases referencing the MRC must be approved by the MRC Press Office before it is released to the media.

AC4 Use of Animals

The MRC supports the principles of the 3Rs (Replacement, Reduction and Refinement). Research organisations and award holders are expected to abide by the core principles set out in the cross-funder guidance 'Responsibility in the use of animals in bioscience research: Expectations of the major research councils and charitable funding bodies' (available at www.nc3rs.org.uk) and RGC 2.2 of the Research Council Terms and Conditions (www.ukri.org/funding/information-for-award-holders/grant-terms-and-conditions/).

The provisions of the Animals (Scientific Procedures) Act 1986 must be observed. All MRC awards are made on the absolute condition that no work which is controlled by the act will begin until the necessary licences have been obtained from the Home Office. Any recommendations arising from the MRC peer review process with regards to animal use must be followed.

When animals are purchased from commercial suppliers, UK suppliers should be used wherever possible, to minimise the risk of suffering during transport.

All research involving non-human primates must comply with the NC3Rs Guidelines: Primate accommodation, care and use (available at www.nc3rs.org.uk).

Researchers should ensure that they report animal-based studies in accordance with the ARRIVE guidelines (www.nc3rs.org.uk/ARRIVE) as far as possible, taking into account the specific editorial policies of the journal concerned.

Any new procedure likely to replace the use of animals in research or testing, reduce the numbers used or refine animal use must be reported to the MRC and disseminated through the usual channels to all those who might make use of it.

MRC is a public body legally obliged to provide information on its work to parliament and to the public, and is committed to improving transparency in public communications on animal use. MRC will make public information about the animal experiments it funds when needed (for example as anonymous examples, or in response to direct queries). MRC will resist all requests for information that might lead to the identification of places or individuals, except with the express permission of the individuals concerned.

AC5 Mouse Strains

MRC supports a central repository of mouse strains - the MRC mouse Frozen Embryo and Sperm Archive (FESA) at the Mammalian Genetics Unit, Harwell. Award holders are expected to contact FESA to highlight mouse strains engineered, or characterised using MRC funds, and are encouraged to deposit these strains with the archive.

Depositors retain ownership of strains and there is currently no charge for depositing strains to make them freely available to the academic community.

FESA aims to ensure that valuable mouse strains are safeguarded, that the need to maintain colonies of live mice for long periods of time is reduced, and that the significant investment in engineering strains is capitalised upon fully. MRC award holders planning mouse research should contact FESA at the earliest opportunity.

For help with the requirements of AC6-AC13 please contact MRC Regulatory Support Centre: mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-

AC6 Health Departments' Research Governance Frameworks

Research involving NHS patients, their organs, tissues or data which falls within the scope of the UK Health Departments' Research Governance Frameworks (RGF, www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/) must comply with MRC policy on the health departments research governance frameworks (mrc.ukri.org/research/policies-and-guidance-for-researchers/clinical-research-governance/health-departments-research-governance/).

MRC requires research organisations to ensure sponsorship responsibilities are clearly identified, the research undertaken complies with the requirements of the employing organisation set out in the RGF, and that agreements and systems are in place with NHS Trusts and other partner organisations, including commercial organisations, to comply with the RGF. Systematic documentation of key decisions and approvals, particularly in relation to work with patients, their organs, tissues and data is crucial.

AC7 Human Participants in Research

MRC expects all research involving human participants to be undertaken in accordance with its policies and guidance available from mrc.ukri.org/research/policies-and-guidance-for-researchers/#ethics. These include:

- Good Research Practice (2012);
- Medical research involving adults who cannot consent (2007);
- Medical Research Involving Children (2004);
- Human Tissue and Biological Samples for Use in Research (2014);
- Personal Information in Medical Research (2000)

Research organisations and award holders have absolute responsibility for ensuring that investigations being undertaken within NHS premises, nursing or residential homes or NHS service establishments, schools, or any other organisations, do not take place without the explicit approval of the appropriate authority in advance.

Payments to healthy volunteers participating in clinical research are allowable, provided that the payment is for expense, time and inconvenience and is not at a level which would induce people to take part in studies against their better judgement. Further guidance on payments and incentives in research can be found at www.hra.nhs.uk/documents/2014/05/hra-guidance-payments-incentives-research-v1-0-final-2014-05-21.pdf

Independent Research Ethics Committee approval is required for research that involves human participants (whether patients or healthy volunteers) or records. In the case of research involving NHS patients, premises or records, this will be a NHS Research Ethics Committee (REC). Such approval is also required for certain studies of human tissues. Further guidance on when NHS REC approval is required can be found at www.hra-decisiontools.org.uk/ethics/

In England and Wales research involving individual patient data, where the patient's consent will not be obtained, is covered by "Section 251" of The National Health Service Act 2006, and requires additional approval via the Health Research Authority's Confidentiality Advisory Group (www.hra.nhs.uk/about-the-hra/our-committees/section-251/). In Scotland, decisions on disclosure of identifiable patient information are made by Caldicott Guardians (see www.informationgovernance.scot.nhs.uk/ for further details).

In the case of social science research, the MRC recommends that award holders follow the ESRC Framework for Research Ethics (revised 2015, escr.ukri.org/files/funding/guidance-for-applicants/escr-framework-for-research-ethics-2015/) which highlights the responsibility of the research organisation for ensuring that the research is subject to appropriate ethics review. In

some cases this review is required by an NHS REC, for further guidance please see www.hra.nhs.uk/research-community/

MRC requires the award holder to notify MRC if amendments required by a regulator or a REC will substantially affect the research question, methodology or cost previously approved.

Any serious incident arising in the course of research that has been approved by a REC should be reported immediately to the MRC, as well as to the REC. The research must be suspended until the REC has decided whether it may be continued or should be abandoned.

Research involving human participants in developing societies presents specific ethical challenges and the MRC guidelines Research Involving Human Participants in Developing Societies (mrc.ukri.org/publications/browse/research-involving-human-participants-in-developing-societies/) must be followed.

AC8 Clinical Trials

When research involves MRC-funded clinical trials, award holders must act in accordance with MRC policy on UK clinical trials regulations (mrc.ukri.org/research/policies-and-guidance-for-researchers/clinical-research-governance/clinical-trials-regulations/) in relation to ethical, sponsorship, reporting, monitoring and publication requirements.

- An independent Trial Steering Committee and Data Monitoring and Ethics Committee must be set up to oversee the conduct of the trial, with an MRC representative acting as an observer.
- MRC-funded trials must be registered with an International Standardised Randomised Control Trial Number (ISRCTN) on the ISRCTN Registry (www.isrctn.com). The unique identification number must be used in publications and provided to MRC by adding it to Researchfish within a year of the trial starting. Failure to provide this number will result in suspension of funding.
- Results of MRC-funded trials (whether positive or negative) must be published without unreasonable delay following the conclusion of the study (generally within a year of completion). Results should be reported in accordance with the recommendations in the CONSORT statement (www.consort-statement.org/). Before results are published they must be discussed by the Trial Steering Committee.
- Any contribution to an MRC-funded trial by another body, such as a pharmaceutical company (donation of drugs etc.), must be the subject of a collaboration agreement between the parties (see AC20).

AC9 Data Sharing

Award holders must comply with the MRC policy on research data sharing (mrc.ukri.org/documents/pdf/mrc-data-sharing-policy/) along with the MRC policy on sharing of research data from population and patient studies (mrc.ukri.org/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/).

AC10 Human Fertilisation

When research involves the use of human gametes, embryos or human admixed embryos researchers must act in accordance with the Human Fertilisation and Embryology Act 1990 as amended in 2008 and 2015 (the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations). This includes obtaining a research licence to undertake activities covered by the Act. Further information can be obtained from www.hfea.gov.uk/

AC11 Medical Records

When research involves the use of medical records, the award holder must act in accordance with the principles set out in the Data Protection Act 1998 and the NHS requirements to protect patient confidentiality. Advice on these requirements is available from the MRC Regulatory Support Centre.

All researchers handling personal data must have clearly established obligations to maintain confidentiality (eg formalised within policy written by their research organisations or through professional codes of conduct).

All NHS bodies should routinely inform patients that medical information may be used in research statistics, etc., and should give patients who wish to discuss any concerns an opportunity to do this (Section 251 of NHS Act 2006). Identifiable data should not be used in research if a patient has made clear that they do not wish it to be.

AC12 Removal, Use or Storage of Human Tissue

Award holders whose research involves the removal, use or storage of human tissue as specified in the relevant legislation must:

- comply with the appropriate legislation, ie the Human Tissue Act 2004 and/or the Human Tissue (Scotland) Act 2006;
- follow the relevant standards and Codes of Practice issued by the Human Tissue Authority (HTA) (the MRC Regulatory Support Centre (mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/) has summarised these);
- follow the MRC guidance detailed in Human Tissue and Biological Samples for Use in medical Research (2014, mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/).

Where research involves the use of human tissues and cells to treat patients (human application), award holders must also:

- comply with the Human Tissue (Quality and Safety for Human Application) Regulations 2007;
- work within the applicable regulations and standards as dictated by the Human Tissue Authority, Medicines and Healthcare products Regulatory Agency (MHRA), Human Fertilisation and Embryology Authority and Health Research Authority. The UK Stem Cell Tool Kit (www.sc-toolkit.ac.uk/home.cfm) gives guidance on applicable regulatory routes, and the MHRA Innovation Office (www.gov.uk/government/groups/mhra-innovation-office) provides a regulatory advice service for regenerative medicine.

When research involves the use of human fetal tissue, or non-fetal products of conception (ie amniotic fluids, umbilical cord, placenta or membranes), researchers should follow the guidance set out in relevant Codes of Practice issued by the HTA (in particular see paragraphs 171-175 in the Code of Practice on Consent at www.hta.gov.uk/).

When research involves procedures for the removal of human tissue at post-mortem examination, researchers must also follow guidance issued by the Health Departments and Local Health Authorities.

AC13 Stem Cells

Award holders whose research involves human stem cell lines (both embryonic and adult) must:

- Abide by the UK Code of Practice for the use of Human Stem Cell lines (mrc.ukri.org/documents/pdf/code-of-practice-for-the-use-of-human-stem-cell-lines/)

- Ensure that they hold all relevant licenses, accreditations and approvals from, and abide by the Codes of Practice issued by, but not limited to, the Human Fertilisation and Embryology Authority (HFEA; see AC10), the Human Tissue Authority (HTA; see AC12), the Health Research Authority (HRA; for research ethics, gene therapy and confidentiality; see AC6, AC7, AC8), the Medicines and Healthcare products Regulatory Agency (MHRA; see AC6, AC7, AC8), the EU Tissue and Cells Directive (where applicable).

In the case of research involving human embryonic stem cells:

- Deposit a sample of every human embryonic stem cell line derived with MRC funding in the UK Stem Cell Bank; applications to deposit or access banked stem cell lines must be approved by the Steering Committee for the UK Stem Cell Bank and for the Use of Stem Cell Lines (mrc.ukri.org/research/policies-and-guidance-for-researchers/uk-stem-cell-bank-steering-committee/).
- Not pass samples of human embryonic stem cell lines to third parties other than those approved by the Steering Committee for the UK Stem Cell Bank and for the Use of Stem Cell Lines and/or the HFEA.
- Not take human embryonic stem cell lines out of the UK unless approved by the Steering Committee for the UK Stem Cell Bank and for the Use of Stem Cell Lines and/or the HFEA.
- Scientists from overseas wishing to conduct human embryonic stem cell research in the UK as visiting workers must provide a written statement from their home institution, outlining that as the employer of the visiting worker they take on the responsibilities of ensuring their employee works to and complies with the requirements of the UK Governance landscape, set out in the UK Code of Practice.
- Send copies of publications to the UK Stem Cell Bank, and agree that the UK Stem Cell Bank may post summaries of published results on their web site.
- Assist the MRC and the UK Stem Cell Bank, on request, with public engagement activities.

AC14 Use of Radioactive Substances and Neutron Irradiation in Humans

When research requires the administration of radioactive medicinal products (including in vivo neutron activation analysis in humans), researchers must follow the guidance issued by the Administration of Radioactive Substances Advisory Committee (ARSAC, www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee/about) and seek the relevant approval(s) as appropriate.

AC15 Genetic Modification

In accordance with the Genetically Modified Organisms (Contained Use) Regulations 2014, research organisations and individuals undertaking genetic modification must be registered with the Health and Safety Executive (HSE), undertake risk assessment and seek consent where appropriate.

Researchers who carry out genetic modification should be familiar with the legislative requirements and with the Scientific Advisory Committee on Genetic Modification (Contained Use) guidance. Advice can be obtained from HSE Head Office or from your nearest HSE Office and Knowledge Centre (www.hse.gov.uk/contact/maps/index.htm).

AC16 Dangerous Pathogens

Research organisations accommodating projects involving the use of dangerous pathogens must comply with the safeguards recommended by the Advisory Committee on Dangerous Pathogens in their guidance 'Infection at work: controlling the risk' (www.hse.gov.uk/pubns/infection.pdf), 'Biological Agents: the principles, design and operation of

containment in a level 4 facility' (www.hse.gov.uk/pubns/web09.pdf) and 'Biological agents: Managing the risks in laboratories and healthcare premises' (www.hse.gov.uk/biosafety/biologagents.pdf).

AC17 Controlled Drugs

When research requires the use of one or more of the drugs controlled under the Misuse of Drugs Act, 1971 and its subsequent amendments, researchers must hold an appropriate Home Office licence in accordance with the most up to date Regulations.

AC18 Open Access Policy – Publication Repositories

To comply with the RCUK Policy on Open Access (see RGC 22 of the Research Council Terms and Conditions) the MRC requires all publications to be deposited at the earliest opportunity, and certainly within six months of publication, in Europe PubMed Central (europepmc.org/). This applies both during and after the period of funding. The condition is subject to compliance with publishers' copyright and licensing policies. Whenever possible, the article deposited should be the published version. For more information see mrc.ukri.org/research/policies-and-guidance-for-researchers/open-access-policy/

AC19 Commercial Exploitation

The research organisation should ensure that, wherever possible, the licensing of intellectual property generated from research funded by the MRC includes provision for research use by other MRC supported scientists.

Research organisations must respond to requests from the MRC to provide assurance that appropriate systems and capabilities are in place to exploit and manage intellectual property generated from MRC-funded research.

AC20 MRC Industry Collaboration Agreement

It is a condition of MRC Industry Collaboration Agreement (MICA) awards that the PI/research organisation must provide MRC Head Office with a copy of the collaboration agreement, signed by all partners, within 3 months of the date of this letter and prior to the award start date. The agreement must be consistent with the Heads of Terms submitted with the application. The grant cannot be activated, and payments, made until this document has been submitted and approved by the MRC.

AC21 Peer Review

Peer review is an integral part of the application process and ensures research of the highest calibre is funded. MRC-funded researchers are expected to contribute to this process when invited to do so, unless they have a conflict of interest (see Reviewers Handbook, mrc.ukri.org/documents/pdf/reviewers-handbook/), or where the research proposed is outside their expertise. We would typically expect an MRC-funded researcher to provide at least three reviews per year.