MRC Additional Terms and Conditions

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 holders* 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.

*Award Holders are all MRC Grant Holders and recipients of MRC Unit and Institute

funding (programme leaders).

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' (https://mrc.ukri.org/news/browse/improving-support-for-clinical-academics/).

AC2 Clinical Responsibilities

Clinical award holders (Clinical Research Training Fellowships, Clinician Scientist Awards, Senior Clinical Fellowships or Clinical Academic Research Partnerships) 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 UKRI Terms and Conditions of Research Council

fEC Grants (https://www.ukri.org/funding/information-for-award-holders/grant-terms-and-conditions/).

AC3 Mouse Strains

MRC supports a central repository of mouse strains - the MRC mouse Frozen Embryo and Sperm Archive (FESA) at 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 AC5-AC13 please contact MRC Regulatory Support Centre: https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/.

AC4 Human Participants in Research

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

-Good Research Practice (2012);

Using information about people in health research (2016-17)

-Human Tissue and Biological Samples for Use in Research (2014);
-Medical research involving adults who cannot consent (2007);
-Medical Research Involving Children (2004);
-Guidelines for the management of global health trials (2017).

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.

AC5 Approvals

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 an 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 http://www.hra-decisiontools.org.uk/ethics.

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

required by an NHS REC, for further guidance please see https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/.

MRC does not need to be routinely notified by the award holder of amendments required by a regulator or a REC unless they relate to urgent safety measures and/or substantially change the research approved for funding by the MRC.

AC6 Payments and incentives in research

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 https://www.hra.nhs.uk/about-us/committees-and-services/.

AC7 Clinical Trials

When research involves MRC-funded clinical trials, award holders must act in accordance with MRC policy on UK clinical trials regulations https://mrc.ukri.org/research/policies-and-guidance-for-researchers in relation to ethical, sponsorship, reporting, monitoring and publication requirements. Research involving trial oversight and management for MRC-funded clinical trials conducted in lower and middle income countries (LMICs), should refer to the MRC guidelines for management of global health trials https://mrc.ukri.org/funding/science-areas/global-health-and-international-partnerships/funding-partnerships/joint-global-health-trials/.

- An independent Trial Steering Committee, and in most cases a Data Monitoring Committee, must be set up to oversee the conduct of the trial, with an MRC representative acting as an observer. In exceptional circumstances for particularly low risk trials, a researcher may seek approval from the MRC Programme Manager for more limited TSC and/or DMC oversight structures.
- MRC-funded trials must be registered with an International Standardised Randomised Control Trial Number (ISRCTN) on the ISRCTN Registry https://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 and within 24 months of completion of the study. Results should be reported in accordance with the recommendations in the CONSORT statement http://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).

AC8 UK Policy Framework for Health and Social Care Research

Research involving NHS (or HSC in Northern Ireland) patients, their organs, tissues or data which falls within the scope of the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/), must comply with MRC policy on the health departments' research governance framework https://mrc.ukri.org/research/policies-and-guidance-for-researchers/.
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 UK policy framework, and that agreements and systems are in place with NHS Trusts and other partner organisations, including commercial organisations, to comply with the framework. Systematic documentation of key decisions and approvals, particularly in relation to work with patients, their organs, tissues and data is crucial.

AC09 Medical Records

When research involves the use of medical records, the award holder must act in accordance with the principles set out in data protection legislation (https://ico.org.uk/for-organisations/guide-to-data-protection/introduction-to-data-protection/) 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 (e.g. formalised within policy written by their research organisations or through professional codes of conduct).

Research involving identifiable patient-level data will require NHS Research Ethics Committee approval and may also require additional approvals. In England and Wales research involving identifiable patient-level data, without patient consent, is covered by "Section 251" of The National Health Service Act 2006 and requires additional approval via the Health Research Authority's https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/ In Scotland, decisions on disclosure of identifiable patient-level data are made by Caldicott Guardians https://www.informationgovernance.scot.nhs.uk/pbpphsc/.

AC10 Data Sharing

Award holders must comply with the MRC policy on research data sharing https://mrc.ukri.org/research/initiatives/health-and-biomedical-informatics/access-governance-and-ethics along with the MRC policy on sharing of research data from population and patient studies https://mrc.ukri.org/research/initiatives/health-and-biomedical-informatics.

When research involves clinical trials, clinical intervention studies, public health intervention studies or observational studies award holders must comply with the MRC policy on open research data from clinical trials and public health interventions https://mrc.ukri.org/research/policies-and-guidance-for-researchers/open-research-data-clinical-trials-and-public-health-interventions.

AC11 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 https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/ has summarised these);
- follow the MRC guidance detailed within the Policies and Guidance for Researchers https://mrc.ukri.org/research/policies-and-guidance-for-researchers/ to download the Human Tissue and Biological Samples for Use in medical Research PDF.

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 http://www.sc-toolkit.ac.uk/home.cfm gives guidance on applicable regulatory routes, and the MHRA Innovation Office (https://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 Consent Code of Practice issued by the HTA (in particular, please see paragraphs 141-143 at https://www.hta.gov.uk/hta-codes-practice-and-standards-0.
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.

AC12 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 (Code of Practice can be downloaded from the MRC website: https://mrc.ukri.org/research/policies-and-guidance-for-researchers/uk-stem-cell-bank-steering-committee/.
- 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 (https://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.

AC13 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 https://www.hfea.gov.uk/.

AC14 Ionising radiation

Under the Ionising Radiation (Medical Exposure) Regulations 2017 and the Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations 2018, Research Ethics Committee approval is required where participants are to be exposed to ionising radiation as part of their involvement in medical or biomedical, diagnostic or therapeutic, research.

Research studies involving the administration of radioactive substances must also be approved by the Administration of Radioactive Substances Advisory Committee (ARSAC).

For further guidance: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/ionising-radiation/

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 (https://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 https://www.hse.gov.uk/aboutus/meetings/committees/acdp/index.htm in their guidance 'Infection at work: controlling the risk' , 'Biological Agents: https://www.hse.gov.uk/biosafety/hseandinfection.htm the principles, design and operation of containment in a level 4 facility' https://www.hse.gov.uk/biosafety/information.htm.

AC17 Controlled Drugs and Substances

When research requires the use of one or more of the drugs controlled under the Psychoactive Substances Act 2016 or 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 UKRI Policy on Open Access (see RGC 12.4 of the UKRI Research Council

fEC 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 (https://mrc.ukri.org/research/policies-and-guidance-for-researchers/open-access-policy/).

AC19 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.