Medical Research Foundation

Grant Terms and Conditions

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These grant terms and conditions relate to the use of all Medical Research Foundation (Foundation) funds. References in these terms and conditions to statutory provisions and guidance include any subsequent amendments or re-enactments.

Definitions:

Principal Investigator:
The person to whom the research undertaken with Medical Research Foundation funds is assigned. The Principal Investigator takes responsibility for the intellectual leadership of the research project and for the overall management of the research.

Co-Investigator:
A person who assists the Principal Investigator in the management and leadership of a project.

Lead Research Organisation:
The organisation to which the Medical Research Foundation funds are awarded, and which takes responsibility for the management of the research project and the accountability of funds provided.

Data Protection Regulations
The Medical Research Foundation will use information provided in the application form for processing the proposal, any consequential funding, and for the payment, maintenance and review of Medical Research Foundation funds. This may include:

- Preparation of material for use by referees and peer review panels;
- Administration, investigation and review of applications;
- Statistical analysis in relation to the evaluation of research and the study of trends;
- Policy and strategy studies.

To meet the Foundation's obligations for public accountability and the dissemination of information, details of Foundation awards, including those named on the application form, may also be made available on the Foundation's website and other publicly available databases, and in reports, documents and mailing lists.

The Foundation is working towards compliance with the General Data Protection Regulation (GDPR), which came into effect on 25 May 2018. All personal data collected by the Foundation during the application for or funding of a Grant will be handled in accordance with the GDPR principles.

1. Responsibilities of the Lead Research Organisation (LRO)

The LRO must ensure that Principal and Co-Investigators are made aware of their responsibilities and that they observe the terms and conditions of grants.

The LRO must ensure that research supported by the grant complies with all relevant legislation and Government regulation, including that introduced while work is in progress. This requirement includes approval or licence from any regulatory body that may be required before the research can commence.

The LRO must provide the infrastructure needed to carry out the research, together with any specific contributions identified in the application.

The LRO is expected to adopt the principles, standards and good practice for the management of research staff set out in the 2008 Concordat to Support the Career Development of Researchers, and subsequent amendments. The LRO must create an environment in which research staff are selected and treated on the basis of their merits, abilities and potential. It must ensure that reliable systems and processes are in place so that the principles of the Concordat are embedded into practice within the LRO. It must ensure compliance with all relevant legislation and Government regulation, including any subsequent amendments introduced while work is in progress.

The LRO is responsible for compliance with the terms of the Equality Act 2010 including any subsequent amendments introduced while work is in progress; and for ensuring that the expectations set out in the RCUK statement of expectations for equality and diversity are met.

The LRO is expected to adopt the principles, standards and good practice for public engagement with research set out in the 2010 Concordat for Engaging the Public with Research: https://re.ukri.org/documents/hefce-documents/concordat-for-engaging-the-public-with-research/

The LRO must create an environment in which public engagement is valued, recognised and supported. It must ensure that reliable systems and processes are in place so that the principles of the Concordat are embedded into practice within the LRO.

The LRO must appoint a Research Fellow as an employee for the full duration of the award. The LRO must integrate the Research Fellow within the research activities of the host department, whilst ensuring that they are able to maintain independence and focus on their personal research programme.

The LRO must notify the Medical Research Foundation of any change in its status, or that of the investigators, that might affect their eligibility to hold Foundation support.

The LRO must ensure that the requirements of the Employing Organisation under the Department of Health's Research Governance Framework for Health and Social Care (or equivalent) are met for research involving NHS patients, their organs, tissues or data, and that the necessary arrangements are in place with partner organisations. Where it also accepts the responsibilities of a Sponsor (as defined in the Governance Framework), it must also ensure that the requirements for Sponsors are met.

The LRO must ensure proper financial management and accountability of grant funds.

The LRO must ensure that adequate business continuity plans are in place to ensure that operational interruptions to the research are minimised.

The LRO is responsible for ensuring that all clinicians supported by Foundation funding are aware that they are individually responsible for maintaining appropriate cover of professional indemnity assurance. 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. The Foundation will not meet the costs of such cover. The LRO is responsible for ensuring that any honorary clinical contracts required by clinical staff have been obtained prior to the start of the award.

2. Research Governance

It is the responsibility of the LRO to ensure that the research is organised and undertaken within a framework of best practice that recognises the various factors that may influence or impact on a research project. Particular requirements are to ensure that all necessary permissions are obtained before the research begins, and that there is clarity of role and responsibility among the research team and with any collaborators. The Medical Research Foundation expects research to be conducted in accordance with the highest standards of scientific integrity and research methodology.

2.1 Research Ethics

The LRO is responsible for ensuring that ethical issues relating to the research are identified and brought to the attention of the relevant approval or regulatory body. Approval to undertake the research must be in place before any work requiring approval begins. Ethical issues should be interpreted broadly and may encompass, among other things, relevant codes of practice, the involvement of human participants, tissue or data in research, the use of animals, research that may result in damage to the environment and the use of sensitive economic, social or personal data.

2.2 Health and Safety

The LRO is responsible for ensuring that a safe working environment is provided for all individuals associated with a research project. Its approach and policy on health and safety matters must meet all regulatory and legislative requirements and be consistent with best practice recommended by the Health & Safety Executive. Appropriate care must be taken where researchers are working off-site. The LRO must satisfy itself that all reasonable health and safety factors are addressed.

The Medical Research Foundation reserves the right to require the LRO to undertake a safety risk assessment in individual cases where health and safety is an issue, and to monitor and audit the actual arrangements made.

2.3 Misconduct and Conflicts of Interest

The LRO is required to have in place procedures for governing good research practice and for investigating and reporting unacceptable research conduct, that meet the requirements set out in the Concordat to Support Research Integrity (2012) https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pd and the Research Councils' Code of Conduct and Policy on the Governance of Good Research Conduct (2009) and any subsequent amendments.

The LRO must ensure that potential conflicts of interest in research are declared and subsequently managed.

3. Use of Animals in Research

The Medical Research Foundation supports the principles of the 3Rs (Replacement, Reduction and Refinement) which promote the development and dissemination of techniques that reduce, refine, or replace animal experiments.

The LRO must ensure that research involving the use of animals complies at all times with the relevant laws and regulation of the host country.

Wherever possible, researchers must adopt procedures and techniques that avoid the use of animals. Where this is not possible, the research must be designed so that:

- The least sentient species with the appropriate physiology for the work are used.
- The number of animals used in an experiment must be the minimum sufficient to create adequate statistical power to answer the question posed.
- The severity of the procedures performed upon animals is kept to a minimum. The experiment should be kept as short as possible, and anaesthesia/analgesia used to minimise pain where possible.

The provisions of the Animals (Scientific Procedures) Act 1986, and any amendments, must be observed and all necessary licenses must have been received before any work requiring approval takes place. All Foundation grants 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 peer review process with regards to animal use must be followed by Foundation grant-holders.

Research Organisations and Principal Investigators 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'.

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 are required, as a condition of Foundation funding, to comply with the NC3Rs Guidelines: Primate accommodation, care and use.

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

Principal Investigators must ensure that any new procedure likely to replace the use of animals in research or testing, reduce the number of animals used or refine animal use are reported to the Foundation and disseminated through the usual channels to all those who might make use of the new procedure.

3.1 Mouse Strains

Medical Research Council (MRC) supports a central repository of mouse strains - the MRC Mouse Frozen Embryo and Sperm Archive (FESA) at the Mammalian Genetics Unit, Harwell. Principal Investigators are expected to contact FESA to highlight mouse strains engineered, or characterised using Foundation 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 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. Principal Investigators planning mouse research should contact FESA at the earliest opportunity.

4. Medical and Health Research

The LRO is responsible for managing and monitoring the conduct of medical and health research in a manner

consistent with the Department of Health's Research Governance Framework for Health and Social Care (or equivalent). There must be effective and verifiable systems in place for managing research quality, progress and the safety and well-being of patients and other research participants. These systems must promote and maintain the relevant codes of practice and all relevant statutory review, authorisation and reporting requirements.

Research involving human participants or data within the social sciences that falls outside the Department of Health's Research Governance Framework must meet the provisions and guidelines of the Economic & Social Research Council's (ESRC) Research Ethics Framework. While this research may involve patients, NHS staff or organisations, it is defined as research that poses no clinical risk or harm to those who are the subjects of research. LROs must ensure that appropriate arrangements are in place for independent ethics review of social science research that meets local research ethics committee standards.

Significant developments must be assessed as the research proceeds, especially those that affect safety and well-being, which should be reported to the appropriate authorities and to the Foundation. The LRO must take appropriate and timely action when significant problems are identified. This may include temporarily suspending or terminating the research.

The LRO is responsible for managing and monitoring statutory requirements for which it accepts responsibility, for example, in relation to legislation on clinical trials, use of human organs, tissues and data. Guidance by the MRC on the conduct of medical research, and by ESRC on the conduct of social science research must be observed.

4.1 Health Department's Research Governance Framework

Research involving NHS patients, their organs, tissues or data and which falls within the scope of the UK Health Department's Research Governance Framework (RGF) must comply with the MRC policy on the health departments research governance framework.

The Foundation 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.

4.2 Human Participants in Research

The Foundation expects all research involving human participants to be undertaken in accordance with the MRC's policies and guidance available from https://mrc.ukri.org/research/policies-and-guidance-for-researchers/good-research-practice/. 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)

LROs and Principal Investigators have absolute responsibility for ensuring that investigations are being undertaken within an organisation such as a factory, school or service establishment or NHS premises, do not take place without the explicit approval of the appropriate authority in advance.

Payments to healthy volunteers participating in clinical trials 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/nreap/ "Payments and incentives in Research" Document.

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 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. In Scotland, decisions on disclosure of identifiable patient information are made by Caldicott Guardians (see the Public Benefit and Privacy Panel for Health & Social Care for further details).

In the case of social science research, the Foundation recommends that Principal Investigators follow the ESRC Framework for Research Ethics (revised 2015) which highlights the responsibility of the LRO 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 the NRES website: https://www.hra.nhs.uk/planning-and-improving-research/

The Foundation requires notification by the award holder 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 an investigation that has been approved by a REC should be reported immediately to the Foundation, 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*, must be followed (see https://mrc.ukri.org/publications/browse/research-involving-human-participants-in-developing-societies/)

LROs and Principal Investigators have absolute responsibility for ensuring that such approval is granted before any research is undertaken.

4.3 Medical Records

When research involves the use of medical records, the Principal Investigator must act in accordance with both 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 research staff 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).

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.

4.4 Human Fertilisation

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

4.5 Removal, Use or Storage of Human Tissue

Principal Investigators whose proposed research involves the use of human tissue and/or use of human tissue to treat patients as specified in the relevant legislation must:

- comply with the appropriate legislation, i.e. 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 has summarised these);
- follow the MRC guidance detailed in Human Tissue and Biological Samples for Use in medical Research (2014).

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 gives guidance on applicable regulatory routes, and the MHRA Innovation Office provides a regulatory advice service for regenerative medicine.

Principal Investigators whose research involves the use of human foetal tissue, or non-foetal products of conception (i.e. amniotic fluids, umbilical cord, placenta or membranes) should follow the guidance set out in relevant Codes of Practice issued by the HTA (in particular see paragraphs 157-161 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.

4.6 Stem Cells

Principal Investigators 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 (https://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 4.4), the Human Tissue Authority (HTA; see Foundation 4.5), the Health Research Authority (HRA; for research ethics, gene therapy and confidentiality), the Medicines and Healthcare products Regulatory Agency (MHRA), 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 Foundation 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 Medical Research Foundation and the UK Stem Cell Bank, on request, with public engagement activities.

4.7 Genetic Modification

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

4.8 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 must hold an appropriate Home Office licence in place in accordance with the most up to date regulations.

4.9 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', 'Biological Agents: the principles, design and operation of containment in a level 4 facility' and 'Biological agents: Managing the risks in laboratories and healthcare premises'.

Managing the Grant

5. Use of Funds

Subject to the following conditions, grant funds may be deployed to meet eligible research costs, without reference to the Medical Research Foundation, in such a manner as to best carry out the research. Grant funds include a provision to contribute towards inflationary increases in salaries during the term of the grant and these are based on the GDP Deflators published by HM Government.

The Foundation will only meet the full direct costs of research. Grant funds cannot be used to support the indirect costs of the research or overhead costs.

Grant funds are provided for a specific research project and cannot be used to meet costs of an activity that will fall beyond the actual end date of the grant, e.g. when travel falls after the end of the grant, the costs cannot be charged to the grant even if tickets etc. can be purchased in advance.

6. Starting Procedures

The process for accepting a grant consists of two separate steps. The LRO must review and approve a funding schedule within 10 working days of receipt of the notification of a grant offer.

The LRO must then formally accept the grant by completing and returning the Award Acceptance Letter within 10 working days of receipt of the formal award. The Medical Research Foundation may withdraw the offer of a grant if it is not formally accepted by the LRO within this timeframe.

Research must commence within 6 months of the scheduled start date stated in the formal award. The start date of a grant is normally considered to be the date of appointment of the first staff member employed through the grant. The Medical Research Foundation may withdraw the grant if it has not been activated within 6 months of the scheduled start date.

7. Starting Procedures

The research may start up to six months after the award start date. The Foundation must be notified of any changes to the award start date. Permission must be requested from the Foundation for delays to the start of an award beyond six months of the notified start date. Medical Research Foundation must be consulted in the event of any major change in the proposed research, including failure to gain access to research facilities and services, or to gain ethical committee approval for the research, particularly those which make it unlikely that the objectives of the research can be achieved. If appropriate, revised proposals may be required. The Foundation reserves the right to make a new grant in place of the existing grant, or to revise, retain or terminate the existing grant.

It is the responsibility of the LRO to manage the resources on the grant, including the staff, and the Foundation need not be consulted if staffing levels on the grant are changed.

8. Transfers of Funds between Fund Headings

The LRO may increase the funds within individual budget headings by transfer from another budget heading, with the exception of equipment funding (or savings on the purchase of equipment) which is not transferable

without prior approval. Funds can only be transferred and used to meet the cost of activity or activities that meet the agreed aims and objectives of the project. Justification of such budget transfers, where they exceed 20% of the total awarded for a particular budget heading will be required in the Final Expenditure Statement (FES). The Medical Research Foundation reserves the right to query any expenditure outlined in the FES which has not been incurred in line with these Grant Terms and Conditions.

9. Extensions

For research grants: after a research grant has started, the duration may be extended at no additional cost by an overall total of up to 12 months, subject to prior written approval. Extensions will be allowed where they are necessary to enable work to be completed following delays due to:

- Breaks or delays in the appointment of staff
- Parental, paid sick leave, or other special leave
- Extended jury service
- Changes from full-time to part-time working.

In the case of other exceptional circumstances, the duration of the grant may be extended at the discretion of the Foundation. Extensions will be limited to the additional time needed to complete the research. Any request for an extension must state the reasons for the delay and explain how the extra time requested will enable the remaining work to be completed.

For fellowship grants: after a fellowship grant has started, the duration may be extended to cover parental leave, extended jury service or paid sick leave for the fellow in line with the terms and conditions of the fellow's employment. Otherwise, the conditions for extending fellowship grants are the same as those that apply to research grants. Requests for extensions should be made by contacting the Foundation once the required duration is known and before the grant/fellowship ends.

The Medical Research Foundation will not meet the additional costs associated with the absence of fellows due to sickness, injury, or parental leave. The LRO, as the employing organisation, is expected to meet these costs should they arise.

10. Employment of Staff

The Medical Research Foundation does not act as an employer with respect to staff funded through the research grant. The LRO must assume full responsibility for staff funded through the grant and, in consequence, accept all duties owed to and responsibilities for those staff, including, without limitation, their terms and conditions of employment and their training and supervision, arising from the employer/employee relationship.

The LRO must provide research staff with a statement, at the outset of their employment, setting out the provisions for career management and development, including personal skills training, and ensure that they have access to appropriate training opportunities.

Staff must be appointed on terms that are no less favourable than those of comparable posts in the LRO. Staff employed by the LRO from Foundation funds must not call themselves Foundation fellows, unless an additional condition to their award allows them to do so.

The Foundation will not meet the costs to the employer of staff absence due to sickness, injury, maternity, paternity or adoption leave for individuals employed on Foundation grants. As employer, the Lead Research Organisation is expected to meet these costs should they arise.

Provided it is related to the research project on which they are currently working, research staff and fellows may, during normal working hours, undertake teaching and demonstrating work, including associated training, preparatory, marking and examination duties, for up to an average of 6 hours a week (pro rata for part-time staff) calculated over the period that they are supported on the grant.

11. Procurement of Equipment

The procurement of equipment, consumables and services, including maintenance, must comply with all relevant national and EU legislation and the LRO's own financial policy and procedures. Accepted procurement best practice in the higher education sector must be observed. For all equipment and services where the contract value is more than £25,000, excluding VAT, professionally qualified procurement staff must be consulted before the procurement process begins and, where appropriate, at the market research stage, and must approve the order/contract before it is placed with a supplier.

11.1 Ownership of Equipment

Equipment purchased from grant funds is primarily for use on the research project for which the research grant was awarded and belongs to the LRO. In certain circumstances the Medical Research Foundation may wish to retain ownership throughout the period of the grant and possibly beyond. In such cases, the grant will be subject to an additional condition.

The Medical Research Foundation must be informed if, during the life of the research grant, the need for the equipment diminishes substantially or it is not used for the purpose for which it was funded. The Foundation reserves the right to determine the disposal of such equipment and to claim the proceeds of any sale. Any proposal to transfer ownership of the equipment during the period of the grant is subject to prior approval by the Foundation. After the research project has ended, the LRO is free to use the equipment without reference to the Foundation but it is nevertheless expected to maintain it for research purposes, as long as is practicable.

11.2 Use of Equipment

Where there is spare capacity in the use of the equipment; the Medical Research Foundation expects this to be made available to other users. Priority should be given to research supported by the Foundation, AMRC-registered charities and Research Councils.

11.3 Use of Equipment Funds

Any proposal to purchase an item of equipment in the last 6 months of the grant is subject to prior written approval by the Foundation. The Foundation will wish to be assured that the item of equipment is essential to the Foundation-funded research.

Equipment funding is ring-fenced and transfers into and out of the equipment headings is not permitted.

12. Transfer of a Grant to another Lead Research Organisation

The LRO must notify the Medical Research Foundation if the Principal Investigator intends to transfer to another Research Organisation. If this organisation is eligible to hold research grants, and is able to provide a suitable environment to enable the project to be successfully completed, the expectation is that the grant would be transferred with the Principal Investigator. Written agreement to this is required from both the relinquishing and receiving organisations. The Foundation will wish to be assured that satisfactory arrangements have been agreed that will enable the project to be undertaken, or to continue,

in accordance with its research objectives. If suitable arrangements cannot be agreed, the Foundation will consider withdrawing its offer of support or terminating the grant.

Where there is a basis for continuing involvement by the relinquishing LRO, agreement should be reached between both organisations on the apportionment of work and responsibilities, and the distribution of related funding. Grants will not be re-costed following transfer. The unspent balance of the grant will be transferred to the receiving organisation. The receiving organisation will be required to confirm, by return of an offer acceptance, that it will provide any additional resources needed to complete the project.

12.1 Change of Principal Investigator

Research grants: The LRO must consult the Medical Research Foundation if it wishes to change the Principal Investigator, for example, following retirement or resignation. Where the Principal Investigator is transferring to another organisation eligible to hold a grant, the provisions of Term 12 will apply. In other circumstances, the LRO may nominate a replacement Principal Investigator. The Foundation will seek to be assured that the replacement meets the eligibility criteria for Principal Investigators and has the expertise and experience to lead the project to a successful conclusion, in accordance with its research objectives.

Fellowship grants: A fellowship is awarded on the basis of a named individual's suitability to undertake and benefit from the period of research therefore changes to the Principal Investigator are not permitted. The resignation of the fellow, or the termination of their employment, constitutes the end of the fellowship grant for the purpose of submitting a final report and the Foundation's financial liabilities.

13. Expenditure Statements

Medical Research Foundation awards are cash limited and will not be supplemented to meet any additional costs.

The Foundation will reimburse the LRO for expenditure properly incurred in respect of the grant, quarterly in arrears upon receipt of a claim form duly signed on behalf of the LRO, subject to any reasonable explanations that the Foundation may require.

Expenditure must be reclaimed within 6 months of being incurred and the Foundation reserves the right to refuse to pay any part of any expenditure which is not claimed within this timeframe. To secure reimbursement of approved equipment costs, copies of invoices must be included with the claim form.

The LRO must complete and return an expenditure statement within 3 months of the end date of a grant.

In the final statement of expenditure, the LROs will be expected to record the actual sums spent and provide explanations for any significant variances (greater than 20%) from the awarded levels according to each financial heading. Once the final statement of expenditure has been received and the expenditure incurred has been reconciled against payments made, it will be considered as final. The Foundation reserves the right to require the LRO to complete and submit a statement of expenditure at any time during the course of a grant, or to provide supplementary information in support of an interim or final expenditure statement.

13.1 Lapse in Research

Grants can be placed into abeyance for up to one year, with prior permission of the Medical Research Foundation, for example to respond to a period of parental leave, or if there is a reason for delaying the

start of the grant beyond 6 months after the notified start date. Grants that have lapsed for longer than 12 months may be withdrawn.

Grants cannot be placed on hold where another member of staff continues to be funded through the grant. Requests must be made prior to the event or as soon as possible after the event. No invoices will be paid during any period when an award is placed on hold.

13.2 Audit and Inspection

The control of the Medical Research Foundation grant expenditure must be governed by the normal standards and procedures of the LRO and must be covered by the formal audit arrangements that exist in the LRO. The Foundation reserves the right, at its discretion and expense, to commission an audit of the grant and/or systems used by the LRO to administer Foundation grants.

The LRO must maintain a separate accounting record specific to the grant and all costs and income properly relating to the grant should be accounted for through that record.

The Foundation reserves the right to have reasonable access to inspect the records and financial procedures associated with research grants or to appoint any other body or individual for the purpose of such inspection. The LRO must, if required, provide a statement of account for the grant, independently examined by an auditor who is a member of a recognised professional body, certifying that the expenditure has been incurred in accordance with the research grant terms and conditions.

14. Reporting on the outcomes of research

The Medical Research Foundation uses an online system (Researchfish) to collect information on the outputs and outcomes of its funding. The Principal Investigator is expected to submit research outcomes data annually, within a specified submission period. The Foundation requires Principal Investigators to update Researchfish within 3 months of the end of their grant.

The Foundation may require a separate report outside of the annual Researchfish submission period, but researchers will be notified of these as necessary.

The Foundation may also require a separate final report at the end of the research project. If so, it must be submitted by the LRO within three months of the end of the grant on the form provided. The Foundation will not release final payment until this information is received.

The Foundation expects full compliance with annual and final reporting; the LRO must ensure that information is returned in accordance with the guidance provided.

14.1 Research Organisation Sanctions

The Medical Research Foundation reserves the right to impose financial sanctions where it identifies areas of non-compliance in relation to the terms and conditions of grants.

If a final report (requested separately and/or through Researchfish) or the final expenditure statement is not received within 3 months of the end date of the grant, the Foundation will not pay the final invoice until this information is received. All payments made by the Foundation may be recovered if the final report or final expenditure statement is not received within 6 months of the end of the grant.

15. Commercial Exploitation

As a publicly-funded charity, the Medical Research Foundation is under an obligation to ensure that useful results of research that it funds are applied for the public good.

It is the responsibility of the LRO and all engaged in the research, to make every reasonable effort to ensure that the intellectual assets obtained in the course of the research, whether protected by intellectual property rights or not, are used to the benefit of society and the economy.

LROs must respond to requests from the Foundation to provide assurance that appropriate systems and capabilities are in place to exploit and manage intellectual property generated from Foundation-funded research. The LRO will ensure that Principal Investigators respond to requests from the Foundation for information about exploitation outputs and outcomes from the funded research.
Unless stated otherwise, the ownership of all intellectual assets, including intellectual property, and responsibility for their application, rests with the organisation that generates them. Where the grant is associated with more than one research organisation and/or other project partners, the basis of collaboration between the organisations, including ownership of intellectual property and rights to exploitation, is expected to be set out in a formal collaboration agreement. It is the responsibility of the LRO to put such an agreement in place before the research begins. The terms of collaboration agreements must not conflict with the Foundation's terms and conditions.

It is the responsibility of the LRO, and all engaged in the research, to make every effort to ensure that any intellectual assets, including intellectual property, arising from the research is identified, protected and exploited (including all inventions, discoveries, technologies, product, data and know-how). Following the identification of an intellectual asset that may be of medical or commercial value, the LRO will notify the Foundation immediately giving details of the nature of the property at issue, the steps taken or proposed to protect the rights therein, an initial view of the commercial exploitation and notice of whether the LRO wishes to undertake the exploitation.

Arrangements for collaborations and/or exploitation must not prevent the future progression of research and the dissemination of research results in accordance with academic custom and practice. A temporary delay in publication is acceptable in order to allow commercial and collaborative arrangements to be established.

The Foundation may, in individual cases, reserve the right to retain ownership of intellectual assets, including intellectual property (or assign it to a third party under an exploitation agreement) and to arrange for it to be exploited for the public benefit. This right, if exercised, will be set out in an additional condition of the award.

There should be suitable recognition and reward to researchers who undertake activities that deliver benefit through application of research outcomes. The LRO must ensure that all those associated with the research are aware of, and accept, these arrangements.

Should the LRO decide to withdraw or allow patent or like protection to lapse, the Foundation shall be entitled to take assignment of the IP concerned and the LRO shall give sufficient notice to allow it to do so effectively.

Revenue-sharing will be discussed in good faith between the Foundation and the LRO including, where appropriate, a revenue-share based on the proportion of Foundation funding that led to the intellectual assets, including intellectual property. Any share due to the Foundation will be after the party leading management and exploitation of the intellectual asset has deducted its direct costs of exploitation (to include patent costs and legal fees) and its management fee. Exploitation includes use for any

commercial purpose or any licence, sale, assignment, material transfer or other transfer of rights.

The Foundation will have the right to audit the LRO relevant accounts to confirm that there has been an appropriate costs and benefit sharing, made in relation to any such exploitation.
If the LRO does not protect or exploit any such intellectual property to the Foundation's satisfaction, the Foundation shall have the right, but not the duty, to protect and exploit such intellectual property. The LRO agrees to do, and will ensure that its employees and students do, all acts required to assist the Foundation in such protection and exploitation.

15.1 Publication and Acknowledgment of Support

The Principal Investigator should, subject to the procedures laid down by the LRO, publish the results of the research in accordance with normal academic practice. The Principal Investigator must acknowledge the support received from the Foundation (and where possible include the Foundation's logo) in all publications, oral or written reports, posters, presentations and other forms of media communication, including media appearances, press releases and conferences, and information posted on websites that relate to the grant activities or results. Foundation-funded research should formally be described as "Medical Research Foundation-funded".

The Principal Investigator must contact the Foundation before making any public announcements regarding the grant activities.

Journal publications should acknowledge the funding source using the standard format with the Foundation's name in full, Grant funds may be used to cover the costs of publication.

The Foundation is committed to ensuring the published results of the research it funds are made available as broadly as possible. Open access publishing is an important means of maximising the impact of research, and Foundation-funded researchers are encouraged to publish their work in an open access environment.

At the time of application, grant applicants must provide a publishable abstract about the proposed research which, if the application is successful, may be published on Foundation's website. The Foundation will aim to publicise new awards and will work with the successful applicant and the LRO to prepare publicity material accordingly.

15.2 Participation in fundraising and publicity

The Foundation may use data or other material on research that it funds for fundraising or publicity purposes. The Principal Investigator is required to promote Medical Research Foundation and its charitable aims by complying with all reasonable requests to attend or speak at events, and provide help with images and copy for publications. The Principal Investigator is required to co-operate in relation to publicity, research engagement and fundraising activities.

Where the Medical Research Foundation is the largest or most significant contributing funder to the research, it reserves the right to lead on publicity.

Principal Investigators and LRO's must comply with any guidelines for branding, communications and engagement.

15.3 Public Engagement

It is the responsibility of the LRO and the Principal Investigator and Co-Investigators to actively communicate the research to the public at both local and national level and to raise awareness of the role of science and research in any related issues of public interest.

The Medical Research Foundation's Alexander Fleming Dissemination Scheme provides additional support for disseminating Foundation-funded research results beyond the scientific press to patients, practitioners and policymakers. Further information and details of how to apply can be found at: https://www.medicalresearchfoundation.org.uk/grants/individual-grant-name-01 Please contact the Medical Research Foundation for more information.

16. Gifts

The Medical Research Foundation shall have absolute right of any legacy, donation or gift to or in the name of the Foundation or the Medical Research Council, and such right shall extend beyond the term of the grant without time limitation.

17. Disclaimer

The Medical Research Foundation accepts no liability, financial or otherwise, for expenditure or liability arising from the research, except as set out in these terms and conditions, or otherwise agreed in writing.

The Foundation will not indemnify the LRO, any Investigator or any person working on the grant (including employees, students, visiting workers and subcontractors) against any claims for compensation or against any other claims (whether under any stature of regulation or a common law) for which the LRO may be liable as an employer or otherwise for which any such person may be liable.

Where studies are carried out in an NHS Trust, the Trust has a duty of care to its patients. The Foundation does not accept liability for any failure in the Trust's duty of care, or any negligence on the part of its employees.

The Foundation reserves the right to terminate a grant at any time, subject to reasonable notice and to any payment that may be necessary to cover outstanding and unavoidable commitments.

If a grant is terminated or reduced in value, no liability for payment or redundancy or any other compensatory payment for the dismissal of staff funded by the grant will be accepted, but, negotiations will be held with regard to other contractual commitments and concerning the disposal of assets acquired under the research grant.

18. Status

These terms and conditions will be governed by the laws of England and Wales; all matters relating to the terms and conditions will be subject to the exclusive jurisdiction of the courts of England and Wales.

If any provision of these terms and conditions is found by a court or other legitimate body to be illegal, invalid or unreasonable, it will not affect the remaining terms and conditions which will continue in force.

These terms and conditions, together with any additional conditions set out in the formal award; contain the whole agreement between the Foundation and the LRO in relation to the stated award. The Foundation and the LRO do not intend that any of these terms and conditions should be enforceable by any third party.

The Medical Research Foundation reserves the right to vary these terms and conditions.