Grant Terms & Conditions

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

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.

References in these terms and conditions to statutory provisions and guidance include any subsequent amendments or re-enactments.

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 Medical Research Foundation's obligations for public accountability and the dissemination of information, details of Medical Research Foundation awards may also be made available on the Medical Research Foundation's website and other publicly available databases, and in reports, documents and mailing lists.

MRF 1 **Responsibilities of the Lead Research Organisation**

The Lead Research Organisation must ensure that Principal and Co-Investigators are made aware of their responsibilities and that they observe the Terms and Conditions of Medical Research Foundation support.

The Lead Research Organisation must ensure that Medical Research Foundation supported research 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 Lead Research Organisation must provide the infrastructure needed to carry out the research, together with any specific contributions identified in the application.

The Lead Research Organisation 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 Lead Research Organisation 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 Lead Research Organisation. It must ensure compliance with all relevant legislation and Government regulation, including any subsequent amendments introduced while work is in progress.

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

The Lead Research Organisation 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 Lead Research Organisation must ensure proper financial management and accountability of Medical Research Foundation funds. The Lead Research Organisation must ensure that adequate business continuity plans are in place to ensure that operational interruptions to the research are minimised.

<u>Clinicians</u>

The Lead Research Organisation is responsible for ensuring that all clinicians working under a Medical Research Foundation award 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 Medical Research Foundation will not meet the costs of such cover.

The Lead Research Organisation is responsible for ensuring that any honorary clinical contracts required by clinical staff working under a Medical Research Foundation award have been obtained prior to the start of the award.

MRF 1.1 **Other Work Responsibilites**

Research staff supported full-time by a grant or fellowship may work up to six hours a week during normal work hours on teaching, demonstrating or NHS clinical sessions. Exceptions are made for surgeons, who may undertake up to three clinical sessions a week, and fellows undertaking a patient-oriented award, who may undertake up to four clinical sessions a week.

MRF 2 **Research Governance**

It is the responsibility of the Lead Research Organisation 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.

MRF 2.1 **Research Ethics**

The Lead Research Organisation 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.

MRF 2.2 **Health and Safety**

The Lead Research Organisation is responsible for ensuring that a safe working environment is provided for all individuals associated with the use of Medical Research Foundation funds. 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 Lead Research Organisation must satisfy itself that all reasonable health and safety factors are addressed. The Medical Research Foundation reserves the right to require the Lead Research Organisation 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.

MRF 2.3 **Misconduct and Conflicts of Interest**

The Lead Research Organisation is required to have in place procedures for governing good research practice that meet the requirements set out in the *Concordat to Support Research Integrity (2012)* (www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx) and the Research Councils' *Code of Conduct and Policy on the Governance of Good Research Conduct (2009)* and any subsequent amendments.

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

MRF 2.4 **Good Research Practice**

The MRF expects the research it supports to be conducted according to the highest achievable standards of research practice in order to ensure the integrity of the research and outputs.

The Good Research Practice (2012) guide is downloadable from www.mrc.ac.uk/research/research-policy-ethics/good-research-practice/ and sets out the MRF's expectations in the form of principles, guidelines and standards to foster good research practce in all MRF-funded research.

MRF 3 **Use of Animals in Research**

Research Organisations and recipients of Medical Research Foundation funds are expected to abide by the core principles set out in the MRC's Booklet: *Responsibility in the use of animals in biomedical research* and *Animal research: reporting of in vivo experiments*. The Medical Research Foundation supports the principles of the 3Rs which promote the development and dissemination of techniques that reduce, refine, or replace animal experiments.

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

The objectives of Medical Research Foundation funded experiments should be clearly defined and, where possible, Investigators must adopt procedures and techniques which avoid the use of animals. Where this is not possible, the research must be designed so that:

- Species with the appropriate physiology for the work are used; where possible simple organisms should be 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.
- Any recommendations arising from the peer review process with regards to animal use must be followed by Medical Research Foundation grant-holders.

The provisions of the Animals (Scientific Procedures) Act 1986 must be observed. Lead Research Organisations and Principal Investigators are responsible for ensuring that all appropriate personal and project licences required under the Act have been granted by the Home Office. All Medical Research 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.

Principal Investigators must ensure that any new procedure likely to reduce the number of animals for research or testing, reduce the numbers used or refine animal use to improve is reported to Medical Research Foundation and is disseminated through the usual scientific channels to all those who might make use of it.

Principal Investigators using animals purchased from commercial suppliers should, wherever possible, use UK suppliers, to minimise the risk of suffering during transport. All Principal Investigators using primates are required, as a condition of Medical Research Foundation funding, to comply with the '*NC3Rs Guidelines: Primate accommodation, care and use*' (www.nc3rs.org.uk/non-human-primate-accommodation-care-and-use).

MRF 3.1 **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. Principal Investigators are expected to contact FESA to highlight mouse strains engineered, or characterised using Medical Research 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.

MRF 4 Medical and Health Research

The Lead Research Organisation 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. Lead Research Organisations 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 Medical Research Foundation. The Lead Research Organisation must take appropriate and timely action when significant problems are identified. This may include temporarily suspending or terminating the research.

The Lead Research Organisation 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.

MRF 4.1 Health Department's Research Governance Framework for Health & Social/ Community Care

Research involving NHS patients, their organs, tissues or data and which falls within the scope of the UK Health Department's Research Governance Framework, must comply with the NHS Research Governance Framework for Health & Social Care (RGF).

The Medical Research Foundation will not be the RGF sponsor of research undertaken with Medical Research Foundation support. New research proposals must identify the sponsor; the Medical Research Foundation's expectation is that the Lead Research Organisation will accept all, or an allocation of the sponsor's responsibilities.

Ensuring that quality and risk management and monitoring systems are in place is the responsibility of the Lead Research Organisation. Key to good governance is the allocation, acceptance and execution of responsibilities within a sound research and project management framework and consistent with standards. Systematic documentation of key decisions and approvals, particularly in relation to work with

patients, their organs, tissues and data is crucial.

The Medical Research Foundation requires Lead Research Organisations to ensure that the research undertaken with Medical Research Foundation funds complies with MRC's ethics and best practice guidance and the requirements of the employing organisation set out in the Research Governance Framework.

The Medical Research Foundation requires Lead Research Organisations to ensure that agreements and systems are in place with NHS Trusts and other partner organisations including commercial organisations, so as to comply with Medical Research Foundation Terms and Conditions and the Research Governance Framework.

For any research involving human participants, the Medical Research Foundation requires:

- The Research Organisation to demonstrate promptly to the Medical Research Foundation, on request, that the required permissions (i.e. regulatory authorisations and Research Ethics Committee approvals) are in place, or were in place when the activity occurred.
- The Principal Investigator to notify the Medical Research Foundation if amendments required by a regulator or research ethics committee will substantially affect the research question, methodology or costs such that the project or programme is no longer the same as approved.

The Medical Research Foundation does not require the following:

- Permissions to be in place when an application for funding is submitted.
- Routine copying of evidence of submissions, permissions and amendments.
- Routine notification of changes to the protocol requested by the MHRA or Ethics Committee unless they substantially change the research approved.

Exceptionally, in cases where the research may be especially sensitive, the Medical Research Foundation will ask for and require evidence of permissions from the Principal Investigator before releasing funding.

There are more detailed responsibilities for Lead Research Organisations conducting research involving a commercial organisation manufacturing, formulating, packaging or supplying an investigational product . MRC has produced guidance to help Lead Research Organisations identify requirements for research under the Health Department's Research Governance Framework. This guidance applies to Medical Research Foundation funded research. Please see: www.mrc.ac.uk/research/research-policy-ethics/clinical-research-governance/health-departments-research-governance/.

MRF 4.2 Human Participants in Research

The Medical Research Foundation expects that all work involving human participants to be undertaken in accordance with the MRC's statements: *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 (2001)*; *Personal Information in Medical Research (2000)*, including an addendum on "Section 60" of the *Health and Social Care Act, 2001 (2003)*.

Lead Research Organisations 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. In the case of non-clinical investigations which do not involve invasion of the body's integrity, payment of a fee (not normally exceeding £4.00 per hour), plus travelling and other out-of-pocket expenses, is permissible.

Independent local research ethics committee approval is required for research that involves human participants (whether patients or normal 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 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.

In the case of social science research, the Medical Research Foundation recommends that Principal Investigators follow the ESRC Framework for Research Ethics (revised 2012) which highlights the responsibility of the Lead 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 the NRES website: www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/social-care-research/.

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

Any serious incident arising in the course of an investigation that has been approved by a REC should be reported immediately to the Medical Research Foundation, as well as to the ethics commitee. The research must be suspended until the ethics committee 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 www.mrc.ac.uk/news-events/publications/research-involving-human-participants-in-developing-societies/).

MRF 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 MRC's statement *Personal Information in Medical Research (2000)* which can be downloaded from: www.mrc.ac.uk/news-events/publications/personal-information-in-medical-research/.

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 (*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.

MRF 4.4 **Human Fertilisation**

Principal Investigators whose project 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. This will include obtaining a research licence to undertake activities covered by the Act.

Further information can be obtained from

The Human Fertilisation and Embryology Authority
Finsbury Tower
London
EC1Y 8HF

MRF 4.5 **Use 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 and follow the relevant Codes of Practice issued by the Human Tissue Authority (HTA).

Principal Investigators whose research involves the use of human fetal tissue, or non-fetal 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).

MRF 4.6 **Removal of Human Tissue**

Principal Investigators whose research involves procedures for the removal of human tissue at post-mortem examination (*Human Tissue Act 2006*) must follow the guidance detailed in the MRC Statement *Human Tissue and Biological Samples for Use in medical Research (2001)* downloadable from: www.mrc.ac.uk/news-events/publications/human-tissue-and-biological-samples-for-use-in-research/ and issued by the Health Departments and Local Health Authorities.

MRF 4.7 **Stem Cells**

Principal Investigators whose research involves stem cells must follow the Guidance on using the Stem Cell Bank and the *Code of Practice for the use of Human Stem Cell lines* (www.mrc.ac.uk/documents/pdf/code-of-practice-for-the-use-of-human-stem-cell-lines/).

Principal Investigators must also observe MRC's terms and conditions for research grants and training awards involving stem cells (www.mrc.ac.uk/documents/pdf/mrce28099s-terms-and-conditions-for-research-grants-and-training-awards-involving-stem-cells/); these require a written statement of compliance from the Research Organisation before the funding will be released.

MRF4.8 **Use of Radioactive Substances and Neutron Irradiation in Humans**

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

Lead Research Organisations and Principal Investigators have responsibility to ensure that no research is undertaken before all of the appropriate approvals are in place.

MRF 5 **Genetic Modification**

The Genetically Modified Organisms (Contained Use) Regulations 1992 and *The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996* require laboratories that carry out genetic modification to be registered with the Health and Safety Executive.

All such work is subject to risk assessment and according to the assessment some work may additionally require specific consent. Lead Research Organisations and Principal Investigators undertaking genetic modification must be registered with the Health & Safety Executive (HSE), have undertaken risk assessment and have been granted consent (where appropriate).

All notifications and annual returns must be sent to:

The Directorate of Science and Technology
Unit E4, Magdalen House
Stanley Precinct
Bootle
L20 3QZ
Tel: 0151 951 4772

Detailed guidance notes are provided by the Advisory Committee on Genetic Modification (ACGM) to every registered Centre. It is important that Principal Investigators who carry out genetic modification are familiar with the legislative requirements and with ACGM guidance.

Advice can be obtained from the Bootle address of the HSE or from:

HSE Health Directorate B2
Floor 7SW
Rose Court
2 Southwark Bridge
London
SE1 9HB
Tel: 020 7717 6348

MRF 6 **Controlled Drugs**

Principal Investigators whose 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.

Research Organisations and Principal Investigators have absolute responsibility to ensure that all licence requirements are followed.

MRF 7 **Dangerous Pathogens**

Research Organisations/Departments accommodating projects involving the use of dangerous pathogens must comply with the safeguards recommended by the Advisory Committee on Dangerous Pathogens in their report: *Categorisation of Biological Agents According to Hazard and Categories of Containment, HMSO, 4th Edition, 1995*.

MRF 8 **Data Protection Act 1998**

The 1998 Data Protection Act requires data controllers to notify the processing of personal data with the Office of the Information Commissioner. Principal Investigators and their teams must register with the Office through their Research Organisation, and are expected to comply with the principles of good practice outlined in the Act.

MANAGING THE GRANT

MRF 9 **Acceptance of a Grant**

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

The Lead Research Organisation 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 Lead Research Organisation within this timeframe.

MRF 10 **Start of the Research**

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 will withdraw the grant if it has not been activated within 6 months of the scheduled start date.

MRF 11 **Research Monitoring and Evaluation**

While it is the responsibility of the Lead Research Organisation and the Principal Investigator to manage the research, the Medical Research Foundation reserves the right to call for periodic information on progress or to visit the project team. The Principal Investigator may also be asked to attend Trustee Board meetings to update the Board on research progress.

The Principal Investigator must make all reasonable efforts, if so invited, to respond to requests for information or to attend events or activities organised by the Medical Research Foundation concerning the research undertaken. Such events may be held after a grant has finished.

MRF 12 **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.

The Medical Research 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 include a provision to contribute towards nationally agreed pay awards during the term of the grant and are based on the GDP Deflators published by HM Government.

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.

The Lead Research Organisation may increase the amounts within individual headings of expenditure by transfer from another 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 transfers, where they exceed 20% of the total awarded for a particular heading

of expenditure, will be required in the final statement of expenditure. The Medical Research Foundation reserves the right to query any expenditure outlined in the Final Expenditure Statement, which has not been incurred in line with the Grant Terms and Conditions.

MRF 13 **Employment of Staff**

The Medical Research Foundation does not act as an employer with respect to staff funded through the research grant. The Lead Research Organisation 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. Staff must be appointed on terms that are no less favourable than those of comparable posts in the Lead Research Organisation. Staff employed by the Research Organisation from Medical Research Foundation funds must not call themselves Medical Research Foundation fellows or MRC fellows, unless an additional condition to their award allows them to do so.

The Medical Research Foundation will not meet additional costs for salary purposes (including absence of staff due to sickness and injury) on top of the final award. As employer, the Research Organisation is expected to meet these costs should they arise.

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

MRF 14 **Equipment**

The procurement of equipment, consumables and services, including maintenance, must comply with all relevant national and EU legislation and the Research Organisation'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.

Equipment purchased from grant funds is primarily for use on the research project for which the research grant was awarded, and belongs to the Research Organisation. 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 Medical Research 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 Medical Research Foundation. After the research has ended, the Research Organisation is free to use the equipment without reference to the Medical Research Foundation but it is nevertheless expected to maintain it for research purposes, as long as is practicable.

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 Medical Research Council, AMRC-registered charities and Research Council.

MRF 15 **Claiming for Expenditure**

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

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

Expenditure must be reclaimed within 6 months of being incurred and the Medical Research Foundation will not 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.

MRF 16 **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 maternity/paternity/adoptive /parental leave, or if there is a reason for delaying the start of the grant beyond 6 months after the proposed start date. Grants that have lapsed for longer than 12 months will be withdrawn by the Medical Research Foundation.

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 quarterly payments will be made, or invoices met, during any period when an award is placed on hold.

MRF 17 **Changes in Research Project**

The 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 Medical Research 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 Lead Research Organisation to manage the resources on the grant, include the staff, and the Medical Research Foundation need not be consulted if staffing levels on the grant are changed.

MRF 18 **Change of Principal Investigator**

The Lead Research Organisation must consult the Medical Research Foundation if it is proposed 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 MRF 19 will apply. In other circumstances, the Lead Research Organisation may nominate a replacement Principal Investigator. The Medical Research Foundation will wish 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 grant 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 Research Fellow, or the termination of their employment, constitutes the end of the fellowship grant for the purpose of submitting a final report and the Medical Research Foundation's financial liabilities.

MRF 19 **Transfer of a Grant**

The Lead Research Organisation must notify the Medical Research Foundation if the Principal Investigator intends to transfer to another 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 Medical Research 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 Medical Research Foundation will consider withdrawing its offer of support or terminating the grant. Where there is a basis for continuing involvement by the relinquishing Research Organisation, 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 Research 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.

MRF 20 **Final Report and Final Statement of Expenditure**

When the grant comes to an end, the Lead Research Organisation and the Principal Investigator will be required to provide a detailed scientific report of the research undertaken and a final statement of expenditure incurred on the research. The Research Organisation must complete and return both reports within 3 months of the end date of the grant.

In the final report, the Principal Investigator will be expected to list scientific achievements such as publications, and summarize the research undertaken, its objectives, the methodology used, scientific advances made (and any consequent changes in objectives of the work), actual and potential impact on wealth, health and quality of life, efforts taken to disseminate results to user communities (application and exploitation) and to inform the general public, staff development and training, and collaborations.

In the final statement of expenditure, the Lead Research Organisations 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 headings. 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 Medical Research Foundation reserves the right to require the Lead Research Organisation 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.

MRF 21 **Audit & Inspection**

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

The Lead Research Organisation 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 Medical Research 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 Lead Research Organisation must, if required by the Medical Research Foundation, 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.

Research Councils will undertake periodic reviews of Research Organisations within the Funding Assurance Programme to seek assurance that research grants are managed in accordance with their terms and conditions. Medical Research Foundation awards may be reviewed as part of this programme.

MRF 22 **Sanctions**

The Medical Research Foundation reserves the right to impose financial sanctions where it identifies area of non-compliance in relation to the terms and conditions of grants. If the final report or the final expenditure statement is not received within the period allowed, the Medical Research Foundation may recover 20% of the expenditure incurred on the grant. All payments made by the Medical Research Foundation may be recovered if the final report or final expenditure statement is not received within 6 months of the end of the grant.

MRF 23 **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. To meet these objectives the Medical Research Foundation wishes to encourage Research Organisations, 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.

Lead Research Organisations will respond to requests from the Medical Research Foundation to provide assurance that appropriate systems and capabilities are in place to enable Research Organisations to exploit and manage intellectual property generated from the research that the Medical Research Foundation funds. The Lead Research Organisation will ensure that Principal Investigators respond to requests from the Medical Research 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 Lead Research Organisation to put such an agreement in place before the research begins. The terms of collaboration agreements must not conflict with the Medical Research Foundation's terms and conditions.

It is the responsibility of the Lead Research Organisation, 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 Lead Research Organisation will notify the Medical Research Foundation immediately giving details of the nature of the property at issue, the steps taken or proposed to protect the rights there in, an initial view of the commercial exploitation and notice of whether the Lead Research Organisation 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 Medical Research 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 Lead Research Organisation must ensure that all those associated with the research are aware of, and accept, these arrangements.

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

Revenue sharing will be discussed in good faith between the Medical Research Foundation and the Lead Research Organisation including, where appropriate, a revenue share based on the proportion of Medical Research Foundation funding that led to the intellectual assets, including intellectual property. Any share due to the Medical Research 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 Medical Research Foundation will have the right to audit the Research Organisations relevant accounts to confirm that there has been an appropriate costs and benefit sharing, made in relation to any such exploitation.

If the Lead Research Organisation does not protect or exploit any such intellectual property to the Medical Research Foundation's satisfaction, the Medical Research

Foundation shall have the right, but not the duty, to protect and exploit such intellectual property. The Lead Research Organisation agrees to do, and will ensure that its employees and students do, all acts required to assist the Medical Research Foundation in such protection and exploitation.

MRF 24 **Publication and Acknowledgement of Support**

The Principal Investigator should, subject to the procedures laid down by the Lead Research Organisation, publish the results of the research in accordance with normal academic practice. Publications and other forms of media communication, including media appearances, press releases and conferences, must acknowledge the support received from the Medical Research Foundation. Grant supported work should formally be described as "Medical Research Foundation-funded".

The MRF is committed to ensuring the published results of the research we fund are made available as broadly as possible. Open access publishing is an important means of maximising the impact of our funded research, and MRF-funded researchers are encouraged to publish their work in an open access environment. The MRF, regretfully, is not able to provide funding for open access fees.

The Medical Research Foundation may also decide to publicise new awards and will work with the successful applicant and the Research Organisation to prepare publicity material accordingly.

MRF 25 **Public Engagement**

It is the responsibility of the Lead Research Organisation and the Principal Investigator and project team 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 Medical Research Foundation funded research results beyond the scientific press to patients, practitioners and policymakers (for more details contact the Medical Research Foundation Operations Manager).

MRF 26 **Gifts**

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

MRF 27 **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 Medical Research Foundation will not indemnify the Lead Research Organisation, 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 Lead Research Organisation 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 Medical Research 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 Medical Research 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 funding 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 with Medical Research Foundation funds.

MRF 28 **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 Medical Research Foundation and the Lead Research Organisation in relation to the stated award. The Medical Research Foundation and the Lead Research Organisation 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.