Medical Research Foundation

Grant Terms and Conditions

Version 9 June 2022

Grant Terms and Conditions

Term	Definition
Collaborator	An individual or an organisation who contributes toward the Grant but is not necessary for its execution. For clarity, a Collaborator usually does not receive any part of the Grant funding.
Co-Investigator	A person who assists the Principal Investigator in the management and leadership of the Research and is named as such in the Application.
Commercial Exploitation	Use of Results for any commercial purpose or any licence, sale, assignment, materials transfer or other transfer of the Results to a commercial/for-profit organisation.
Data Protection Regulations	(a) any law, statute, directive, legislative enactment, order, regulation, or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the processing of personal data to which a party is subject, including the Data Protection Act 2018 and the UK GDPR for as long as the same remains applicable law; and (b) any code of practice or guidance published by the Information Commissioner's Office from time to time.
Directly Incurred Costs of Research	Costs that are explicitly identifiable as arising from the conduct of the Research which are charged as the cash value actually spent and are supported by an audit record.
Equity	The issuing of equity or any other interest (whether by way of debenture, warrant, security or otherwise) from time to time in any company in consideration of the assignment or grant of a licence, rights or an option thereto to such third party in respect of any Results.
Exploiting Party	The party responsible for managing the protection and Commercial Exploitation of Results pursuant to Section 6 of these terms and conditions. For clarity, the Exploiting Party may be the LRO or a Co-Investigator or a Collaborator (or their respective Technology Transfer Group; TTG) or other third party.
Final Scientific Report	A report which the Principal Investigator must provide at the end of the Grant, detailing the outputs, outcomes and impacts of the project to date.
The Foundation	The Medical Research Foundation
UK GDPR	The UK General Data Protection Regulation being the retained EU law version of the General Data Protection Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data.
Grant	The award made to the Investigator(s) consisting of grant monies payable to the Lead Research Organisation in accordance with and as set out in the Grant Award Letter.

Grant Award Letter	The letter confirming the Foundation's offer of the Grant and setting out the funding available under the Grant and any additional terms and conditions applicable to the Grant.
Grant Terms and Conditions	These terms and conditions together with any additional terms and conditions set out in the Grant Award Letter.
Gross Revenue	The revenue that the Exploiting Party receives from the Commercial Exploitation of Results, including, but not limited to, licence fees, option fees, up-front fees, royalties, minimum royalties, milestone payments, sub-licence fees, Equity, sums received which derive from the disposal or other realisation of any Equity or any other monetary or in-kind compensation received by the Exploiting Party from the licensing or other disposition of the Results for Commercial Exploitation in forms including but not limited to monies, shares or options. For clarity, this is total income prior to any deductions or retained amount made by the corresponding Exploiting Party.
Indirect Costs of Research	Non-specific costs arising from conduct of the Research, which are charged across all similar types of projects based on estimates and which are not otherwise included as Directly Allocated Costs. They include the costs of the Lead Research Organisation's administration such as personnel, finance, IT, legal, general laboratory, office consumables, library and some departmental services.
Investigator(s)	The Principal Investigator and/or the Co-Investigator(s) and/or any other personnel (including employees, students, visiting workers) that work on the Research.
Intellectual Property (IP)	Any patents, utility models, rights to inventions, copyright and related rights, moral rights, trade marks and service marks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off or unfair competition, rights in designs, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets), semiconductor topography rights, and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.
Lead Research Organisation (LRO)	The organisation to which the Grant funding is provided, and which takes responsibility for the management of the Research and the accountability of the Grant funding provided by the Foundation.
Net Revenue	Gross Revenue less: (a) Protection Direct Costs b) TTG fee and (c) any applicable taxes on Gross Revenue and Protection Direct Costs.
Principal Investigator	The person that submitted the Application to the Foundation for funding and is named as such on the Grant Award Letter. For fellowship Grants, the Principal Investigator is the Research Fellow.
Protection Direct Costs	All reasonable external patent and legal costs and other incidental expenses that are incurred by the Exploiting Party directly in connection with protection of the Results, including official patent filing, prosecution, maintenance and renewal fees. Protection Direct Costs shall not include the Exploiting Party's (or its TTG's) internal costs relating to these activities, regardless of the legal constitution of the Exploiting Party or its TTG. The Exploiting Party (and its TTG) may not make deductions for salary or taxes in respect of the Exploiting Party

	(and/or its TTG) or for any amounts payable to the inventors or generators of the Results.
Research	The activities described in the Application and Grant Award Letter.
Research Organisation	Any university, institution, research council or other organisation at which Grant activities are carried out and/or to which Grant monies are received
Results	Any and all information, data, techniques, know-how, results, inventions, discoveries, software and materials (regardless of the form or medium in which they are disclosed or stored) identified or first reduced to practice or writing or developed in the course of the Research, and any and all Intellectual Property pertaining to the foregoing.

1. How These Terms and Conditions apply

1.1 These terms and conditions relate to all activities conducted under or in connection with the Grant, including use of all funds provided by the Foundation under Grant, conduct of the Research and Commercial Exploitation activities. References in these terms and conditions to statutory provisions and guidance include any subsequent amendments or re-enactments.

2. Responsibilities of the Lead Research Organisation (LRO)

2.1 The LRO must ensure that the Principal Investigator and all Co-Investigators are made aware of their responsibilities and that they observe the Grant Terms and Conditions.

2.2 The LRO must ensure the Principal Investigator takes responsibility for the intellectual leadership and the overall management of the Research.

2.3 The LRO shall ensure an agreement with the Co-Investigators or Collaborators, which enables fulfilment of the Research and the Grant Terms and Conditions, is concluded within three months of the Research starting.

2.4 The LRO must ensure that the conduct of the 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.

2.5 The LRO must provide (and ensure any Co-Investigators provide) the infrastructure needed to carry out the Research, together with any specific contributions identified in the Application.

2.6 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 in respect of any Investigators supported by the Grant. The LRO must create an environment in which Investigators supported by the Grant 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.

2.7 The LRO is responsible for ensuring compliance with the terms of the Equality Act 2010, including any subsequent amendments introduced while the Research is in progress, in respect of its appointment of any Investigators. The LRO is also responsible for ensuring that equality, diversity and inclusion is considered and supported at all stages throughout its performance of any activities funded by the Grant, and any decision in respect of the same is in alignment with United Kingdom Research and Innovation (UKRI) policies and principles at: https://www.ukri.org/about-us/policies-and-standards/equality-diversity-and-inclusion/ for equality, diversity and inclusion.

2.8 The LRO is expected to adopt the principles, standards and good practice for public engagement in

respect of the Research as set out in the 2010 Concordat for Engaging the Public with Research (Engagement Concordat): https://re.ukri.org/documents/hefce-documents/concordat-for-engaging-the-public-with-research/.

2.9 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 Engagement Concordat are embedded into practice within the LRO.

2.10 Where applicable, the LRO must appoint a Research Fellow as an employee for the full duration of the Grant. The LRO must integrate the Research Fellow within its research activities whilst ensuring that the Research Fellow is able to maintain independence and focus on conducting the Research.

2.11 During the period of the Grant, the LRO must promptly notify the Foundation in writing of any change in its status, or that of the Principal Investigator and the Co-Investigators, that might affect their eligibility to receive funding from the Foundation under the Grant.

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

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

2.14 The LRO must ensure that the requirements of the Employer, as set out under the UK Health Research Authority Framework for Health and Social Care Research, 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 Framework), it must also ensure that the requirements for Sponsors are met.

2.15 The LRO shall ensure the Research is undertaken with a view to safeguarding vulnerable groups (including children) impacted by the Research. The LRO shall without undue delay notify the Foundation of any safeguarding incidents, allegations or concerns arising from or relating to the Research

2.16 The LRO is responsible for ensuring that all clinicians involved in the Research 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 (as applicable) LRO. 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 working on the Research have been obtained prior to the start of such work.

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

2.18 The Foundation expects the LRO to abide by the 'UK clinical academic training in medicine and dentistry: principles and obligations' (https://mrc.ukri.org/news/browse/improving-support-for-clinical-academics/).

3. Research Governance

General Governance

3.1 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 the Research. 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 Principal Investigator, the Co-Investigators and any Collaborators. The Research must be conducted in accordance with the highest standards of scientific integrity and research methodology.

3.2 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.

Health and Safety

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

Misconduct and Conflicts of Interest

3.4 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.pdf) and the Research Councils' Code of Conduct and Policy on the Governance of Good Research Conduct (2009) and any subsequent amendments.

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

Use of animals in the Research

3.6 The LRO must ensure that any part of the Research involving the use of animals complies at all times with the relevant laws and regulation of the host country. Research that involves the use of animals and that is conducted outside the United Kingdom should, at a minimum standard, be carried out in accordance with the principles of UK legislation.

3.7 Without limiting the generality of Section 3.6 and in relation to any part of the Research involving the use of animals in the United Kingdom, the provisions of the Animals (Scientific Procedures) Act 1986, and any amendments, must be observed and all necessary approvals and licenses must have been received before any Research work requiring such approvals and/or licenses takes place. All 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.

3.8 Any recommendations arising from the peer review of the application with regards to animal use and communicated to the Principal Investigator (whether in the Award Letter or other form or written or electronic communication) must be followed by the Investigators.

3.9 The 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, in relation to any part of the Research involving the use of animals. Investigators should follow the guidance set out in “Responsibility in the use of animals in bioscience research”: https://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research.

3.10 Where possible, and without limiting the generality of Section 3.9, the LRO must ensure Investigators 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.

3.11 When animals are purchased from commercial suppliers for use in the Research taking place in the UK, UK suppliers should be used wherever possible to minimise the risk of suffering during transport.

3.12 All Research activities involving non-human primates are required, as a condition of Foundation funding, to comply with the NC3Rs Guidelines: Primate accommodation, care and use.

3.13 The LRO must ensure that the Investigators report animal-based Research 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.

3.14 The LRO must ensure that any new procedure(s) arising from the Research, which is likely to support or implement the principles of the 3Rs, including procedures that replace the use of animals in research or testing, reduce the number of animals used in research or testing or refine animal use for such activities, is(are) promptly reported to the Foundation and disseminated through the usual channels to all those who might make use of the new procedure(s).

Mouse Strains

3.15 The Medical Research Council (MRC), as part of UKRI supports a central repository of mouse strains - the MRC Mouse Frozen Embryo and Sperm Archive (FESA) located at the Mary Lyon Centre MRC Harwell Institute. The LRO shall ensure the Principal Investigator and Co-Investigators know they are expected to contact FESA (or other suitable public repository) to highlight mouse strains engineered, or characterised using Foundation funds, and are encouraged to deposit these strains with FESA (or other suitable public repository) to ensure they remain available to support further research. Depositors retain ownership of the mouse strains deposited with FESA and there is currently no charge for depositing strains in FESA if the depositor agrees to make them freely available to the academic community / non-profit research community.

3.16 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 new mouse strains is capitalised upon fully. The LRO must encourage Principal Investigator and Co-Investigators planning Research expected to generate new mouse strains to contact FESA (or other suitable public repository) and discuss depositing those strains at the earliest opportunity.

Medical and Health Research

3.17 The LRO is responsible for managing and monitoring the conduct of medical and health aspect of the Research in a manner consistent with the Department of Health's Research Governance Framework for Health and Social Care (or equivalent). The LRO must ensure there are effective and verifiable systems in place for managing research quality, progress and the safety and well-being of patients and other research participants involved in the Research. These systems must promote and maintain the relevant codes of practice and all relevant statutory review, authorisation and reporting requirements.

3.18 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 (ESRC), as part of UKRI, 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 the research. LROs must ensure that appropriate arrangements are in place for independent ethics review of such social science research that meets local research ethics committee standards.

3.19 Significant developments must be assessed as the Research proceeds, especially those that affect safety and well-being of patients and other research participants involved in the Research, which should be reported to the appropriate authorities and to the Foundation. The LRO must take appropriate and

timely action when significant problems associated with the Research are identified. This may include temporarily suspending or terminating the Research.

3.20 The LRO is responsible for managing and monitoring statutory requirements applicable to the Research 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 aspects of the Research, and by ESRC on the conduct of social science aspects of the Research must be observed.

Health Departments Research Governance Framework

3.21 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.

3.22 The LRO is required to ensure sponsorship responsibilities under such Research 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, Co-Investigators, Collaborators and other partner organisations, including commercial organisations, to comply with the RGF. Systematic documentation of key decisions and approvals, particularly in relation to Research work involving patients, their organs, tissues and data, is crucial.

Human Participants in Research

3.23 Research involving human participants must be undertaken in accordance with the MRC's policies and guidance available 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)

3.24 The LRO has absolute responsibility for ensuring that all Research involving human participants undertaken within another organisation or on another organisations premises, such as a factory, school or service establishment or NHS premises, do not take place without the explicit approval and consent of each such human participant and the appropriate authority in advance.

3.25 Payments to healthy volunteers participating in clinical trials / studies that form (part of) the Research are allowable provided that the payment is for expense, time and inconvenience and is not at a level which would induce people to take part in such trials / 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.

3.26 Independent Research Ethics Committee (REC) approval is required for any part of the Research that involves human participants (whether patients or healthy volunteers) or their medical/health records. In the case of Research involving NHS patients, premises or records, this will be an NHS Research Ethics Committee (NHS 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/.

3.27 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, where the patient's consent will not be obtained, are made

by Caldicott Guardians (see the Public Benefit and Privacy Panel for Health & Social Care for further details).

3.28 In the case of social science aspects of the Research, the LRO should 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 see the Health Research Authority website.

3.29 The LRO (via the Principal Investigator) must notify the Foundation if amendments to the Research are required by a regulator or a REC and such amendments will substantially affect the research question, methodology or cost show in the Application and/or previously approved by the Foundation.

3.30 Any serious incident arising in the course of the Research that has been approved by a REC must 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.

3.31 Research involving human participants in low and middle-income countries 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/).

3.32 The LRO has absolute responsibility for ensuring that all required approvals are granted before any aspect of the Research involving human participants in developing societies is undertaken.

Medical Records

3.33 When the Research involves the use of medical/health records from the United Kingdom, the LRO must ensure the Investigators involved in such work act in accordance with both the principles set out in the Data Protection Regulations and the NHS requirements to protect patient confidentiality. Advice on these requirements is available from the MRC Regulatory Support Centre. When the Research involves the use of medical/health records from countries other the United Kingdom, the LRO must ensure the Investigators involved in such work act in accordance with all applicable laws, guidance and requirements.

3.34 The LRO must ensure all Investigators handling personal data for the purposes of the Research have clearly established obligations to maintain confidentiality (e.g. formalised within a policy written by their respective employing organisation or through professional codes of conduct).

3.35 The LRO must ensure that all NHS bodies involved in the Research routinely inform patients that medical information collected in the course of/for the Research 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).

3.36 Identifiable data collected/obtained from patients must not be used in the Research if a patient has made clear that they do not wish it to be.

Human Fertilisation

3.37 When the Research involves the use of human gametes, embryos or human admixed embryos, the LRO must ensure the Investigators involved in such work act in accordance with all applicable laws and regulations, including in respect of activities conducted within the United Kingdom, 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/.

Removal, Use or Storage of Human Tissue

3.38 Where the Research involves the removal, use or storage of human tissue as specified in the relevant legislation must:

- comply with the appropriate legislation, ie the Human Tissue Act 2004 and/or the Human Tissue (Scotland) Act 2006;
- follow the relevant standards and Codes of Practice issued by the Human Tissue Authority (HTA) (see the MRC Regulatory Support Centre for summaries);
- follow the MRC guidance detailed within the Policies and Guidance for Researchers to download the Human Tissue and Biological Samples for Use in medical Research PDF.

3.39 Where Research involves the use of human tissues and cells to treat patients (human application), the LRO must also ensure the Investigators involved in such work:

- 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.

3.40 Where the Research involves the use of human foetal tissue, or non-foetal products of conception (i.e. amniotic fluids, umbilical cord, placenta or membranes), the LRO shall ensure the Investigators involved in such work 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).

3.41 Where the Research involves procedures for the removal of human tissue at post-mortem examination, the LRO shall ensure the Investigators involved in such work also follow guidance issued by the Health Departments and Local Health Authorities.

Stem Cells

3.42 Where the Research involves human stem cell lines (both embryonic and adult), the LRO must ensure the Investigators involved in such work:

- 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/);
- 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), the Human Tissue Authority (HTA), 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).

3.43 In the case of Research involving human embryonic stem cells, the LRO must ensure the Investigators involved in such work:

- deposit a sample of every human embryonic stem cell line derived through the Grant 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 reporting results of such Research to the UK Stem Cell Bank, and agree that the UK Stem Cell Bank may post summaries of published results on their web site; and
- assist the Foundation and the UK Stem Cell Bank, on request, with public engagement activities.

Genetic Modification

3.44 In accordance with The Genetically Modified Organisms (Contained Use) Regulation 2014, where the Research conducted within the United Kingdom involves genetic modification of organisms, the LRO must ensure the Research is registered with the Health & Safety Executive (HSE), as well as ensuring the Investigators involved in such work undertake risk assessment and seek consent where appropriate. Where Research involving genetic modification of organisms outside of the United Kingdom, the LRO must ensure such activities are registered and conducted in accordance the relevant legislation.

Controlled Drugs

3.45 When the Research requires the use of one or more of the drugs controlled under the Misuse of Drugs Act, 1971 and its subsequent amendments, the LRO must ensure the Investigators involved in such work hold an appropriate Home Office licence in accordance with the most up to date regulations.

Dangerous Pathogens

3.46 Where the Research involves the use of dangerous pathogens, the LRO must ensure the Investigators involved in such work 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'.

4. Managing the Grant

Use of funds

4.1 Subject to the following conditions, Grant funds may be deployed to meet eligible costs of the Research, without reference to the Foundation, in such a manner as to best carry out the Research.

4.2 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. Salary costs for subsequent years of the Grant after year one will be calculated upon issuance of Grant Award Letter based on the GDP deflator at market prices at that date.

4.3 The Foundation will only meet the full Directly Incurred Costs of the Research. Grant funds cannot be used to support the Indirect Costs of the Research or any other indirect/overhead costs.

4.4 The cost of the UK Apprenticeship Levy cannot be charged to Grant funds.

4.5 Grant funds are provided for the specific Research and cannot be used to meet costs of any activity that will fall beyond the scope of the Research or 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. have been purchased in advance.

Grant Acceptance Procedures

4.6 The process for accepting a Grant consists of two separate steps. The LRO must review and approve the Grant, including the Grant Terms and Conditions and the funding schedule set out in the Grant Award Letter, within 10 working days of receipt of the Grant Award Letter.

4.7 The LRO must then formally accept the Grant by completing and returning the Award Acceptance Form (provided with the Grant Award Letter) within 10 working days of receipt of the Grant Award Letter. The Foundation may withdraw the offer of the Grant if a completed Award Acceptance Form is not received from the LRO within this timeframe.

Research Starting Procedures

4.8 The Research may start up to six months after the scheduled start date stated in the Grant Award Letter. The start date of the Grant is normally considered to be not later than the date of appointment of the first Investigator employed through the Grant. The Medical Research Foundation may withdraw the Grant if the Research has not started within 6 months of the scheduled start date stated in the Grant Award Letter.

4.9 The Foundation must be notified of any changes to the Research start date. Permission must be requested for delays to the start of the Research beyond six months of the scheduled start date notified in the Grant Award Letter.

4.10 The Foundation must be consulted in the event of any major change in or delay to the Research, including any delay or failure to gain access to any necessary research facilities and/or services, or to gain necessary ethical committee or other regulatory approval for the Research, particularly those which make it unlikely that the objectives of the Research can be achieved within the expected period of the Grant. If appropriate, the Foundation may require submission of proposals for a revised Research plan. In the event submission of such a revised Research plan is 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.

4.11 It is the responsibility of the LRO to manage the resources on the Grant, including the Investigators, and the Foundation need not be consulted if staffing levels funded under the Grant are changed subject to Section 4.12.

Transfers of Grant Funds between Budget Headings

4.12 Subject to Section 4.11, The LRO may increase the funds within individual budget headings set out in the Grant Award Letter 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 Research.

4.13 Approval by the Foundation for such budget transfers, where they exceed 20% of the total amount awarded for a particular budget heading, must be sought prior to the transfer. Justification should also be provided in the Final Expenditure Statement (FES).

4.14 The Foundation reserves the right to query any expenditure outlined in the FES which has not been incurred in line with the Grant Terms and Conditions.

Extensions

4.15 After acceptance of the Grant, the duration of the Grant may be extended at no additional cost by an overall total of up to 12 months, subject to prior written approval of the Foundation. Extensions will be allowed where they are necessary to enable Research work to be completed following delays due to:

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

4.16 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.

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

Employment of Investigators

4.18 The Foundation does not act as an employer with respect to Investigators funded or otherwise supported through the Grant. The LRO (or where applicable, each Co-Investigator) must assume full responsibility for Investigators funded or otherwise supported through the Grant and, in consequence, accept all duties owed to and responsibilities for those personnel, including, without limitation, their terms and conditions of employment and their training and supervision, arising from the employer/employee relationship.

4.19 The LRO must ensure all new Investigators whose employment is funded or otherwise supported through the Grant are provided 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.

4.20 New Investigators funded or otherwise supported through the Grant must be appointed on terms that are no less favourable than those of comparable posts in (as applicable) the LRO or Co-Investigator. Investigators funded or otherwise supported through the Grant must not call themselves Foundation fellows, unless the Grant Award Letter describes the Grant as a Research Fellowship.

4.21 The Foundation will not meet the costs to the employer of Investigator absence due to sickness, injury, maternity, paternity or adoption leave. The Foundation expects that the employer of such personnel, whether the LRO or a Co-Investigator, will meet these costs from its own resources should they arise.

4.22 Provided it is related to the Research on which they are currently working, Investigators may, during normal working hours, undertake academic and other non-commercial activities, which are commensurate with their appointment and/or skills and experience, 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. For clarity, such activities shall include teaching and demonstrating work, including associated training, preparatory, marking and examination duties.

The LRO should ensure that Investigators awarded a Research Fellowship are able to dedicate at least 80 percent of their normal working hours to Grant activities related to their Fellowship. Any other employment activities allocated to the Investigator should not exceed 20 percent of their FTE. This is not in addition to the 6 hours a week described in section 4.22.

Procurement within the Grant

4.23 The Procurement of equipment, consumables and services, including maintenance, for the Research must comply with all relevant legislation and (as applicable) the LRO's and/or Co-Investigator'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.

Carbon Offsetting

4.24 The Foundation supports reducing the carbon footprint of Research where possible. This includes the carbon footprint of travel necessary for carrying out the Research funded by the Grant. The Principal Investigator must ensure that:

- Investigators follow the LRO carbon offsetting policy, where applicable
- Where the LRO does not have a carbon offsetting policy, Investigators must calculate the carbon footprint of their travel (for example using the International Civil Aviation Organization Carbon Emissions Calculator) and select a carbon offset provider.

4.25 If an Investigator chooses to travel by a low-carbon option which is more expensive (for example a train journey rather than airplane), the Foundation will meet these costs where costs are Reasonable: i.e, justifiable, proportional and documented, and a reasonable use of the charitable funds supporting the Grant.

4.26 Applications which were made after December 2020 may include carbon offsetting costs within the budget. Grants awarded prior to this period may use Grant funds to meet reasonable carbon offsetting costs by viring between Grant headings. If additional funds are required for the Principal Investigator must contact the Foundation prior to incurring cost.

Equipment Use

4.27 Equipment purchased from Grant funds (Equipment) is primarily for use on the Research and belongs to (as applicable) the LRO or the Co-Investigator that purchased the same. In certain circumstances the Foundation may wish to retain ownership of the Equipment throughout the period of the Grant and possibly beyond. In such cases, the Grant Award Letter will specify this additional condition.

4.28 The Foundation must be informed if, during the period of the 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 has ended, the (as applicable) LRO or Co-Investigator owning the Equipment is free to use the Equipment without reference to the Foundation but it is nevertheless expected to maintain it and make it available for research purposes, as long as is practicable.

4.29 Any proposal to purchase an item of Equipment over the value of £10,000 in the last six months of the Grant is subject to prior written approval. The Foundation will wish to be assured that the item of Equipment is essential to completion of the Research.

4.30 Equipment funding is ring-fenced and transfers into and out of the equipment budget headings shown on the Grant Award Letter is not permitted.

4.31 Where there is spare capacity in the use of the Equipment during the period of the Grant; it is expected that this Equipment will to be made available to other users. Priority should be given to research supported by the Foundation, Association of Medical Research Charities registered charities and UKRI.

Transfer of the Grant

4.32 **Transfer to another LRO:** The LRO must notify the Foundation if the Principal Investigator intends to transfer to another organisation. If this organisation is eligible to receive funding from the Foundation and is able to provide a suitable environment to enable the Research to be successfully completed, the expectation is that the Grant would be transferred with the Principal Investigator and such new organisation will become the LRO.

4.33 Written agreement to this transfer envisaged by Section 4.32 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 Research to be undertaken, or to continue in accordance with its objectives. If suitable arrangements cannot be agreed, the Foundation will consider withdrawing its offer of support or terminating the Grant.

4.34 If the new LRO is located outside of the UK, or to a UK organisation that is not eligible for UKRI Grant funding, appropriate Due Diligence will be carried out to ensure that the new LRO has in place appropriate governance, financial management and research management structures, policies and procedures to be able to manage the Grant in accordance with the Grant Terms and Conditions.

4.35 Where there is a basis for continuing involvement in the Research by the relinquishing organisation, agreement should be reached between both the relinquishing and receiving organisations on the apportionment of remaining Research work and responsibilities, and the distribution of related Grant funding. Grants will not be re-budgeted following transfer. The unspent balance of the Grant received by the relinquishing organisation will be transferred to the receiving organisation. The receiving organisation will be required to confirm, by return of a Grant Acceptance Letter, that it will provide any additional resources needed to complete the Research.

4.36 Written approval must be obtained from the Foundation of transfer of the Grant before any expenditure of Grant funding is incurred at the new LRO.

4.37 **Transfer of PI:** The LRO must consult the Foundation if it wishes to change the PI, for example, following retirement or resignation or other incapacity of the then current PI to fulfil his/her duties in accordance with the Grant Terms and Conditions. Where the PI is transferring to another organisation eligible to receive funding from the Foundation, the provisions of Section 4.32 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 PI and has the expertise and experience to lead the Research to a successful conclusion, in accordance with its objectives and the Grant Terms and Conditions.

4.38 Where the Grant is specified in the Grant Award Letter as a Research Fellowship, this is awarded on the basis of the named individual's suitability to undertake and benefit from the period of research. Therefore, changes to the Principal Investigator for such Grants are not permitted. The resignation of the Research Fellow, or the termination of their employment, constitutes the end of the Grant for the purpose of submitting a final report and the Foundation's financial liabilities.

Lapse in Research

4.39 Grants can be placed into abeyance/on hold for up to one year, with prior permission of the Foundation, for example to respond to a period of parental leave, or if there is a reason for delaying the start of the Research beyond six months after the notified start date. Grants that have lapsed or been on hold for longer than 12 months may be withdrawn.

4.40 Grants cannot be placed on hold where any Investigator or other member of staff continues to be funded through the Grant.

4.41 Requests to place the Grant into abeyance/hold must be made by the LRO either prior to the event or as

soon as possible after the corresponding event. No invoices will be paid under a Grant during any period when the Grant is placed into abeyance/hold.

5. Grant Expenditure

General

5.1 Grants are cash limited and will not be supplemented to meet any additional costs.

5.2 The LRO will be reimbursed for expenditure properly incurred in respect of the Research, 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.

5.3 Expenditure must be reclaimed within six 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.

5.4 The LRO must complete and return a final expenditure statement (FES) within three months of the end date of the Grant. In the FES, the LRO 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 budget heading. Once the FES has been received and the expenditure incurred has been reconciled against payments made, it will be considered as final.

5.5 The Foundation reserves the right to require the LRO to complete and submit an interim statement of expenditure at any time during the course of the Grant, and/or to provide supplementary information in support of an interim or final expenditure statement.

Audit and Inspection

5.6 The control of the expenditure of Grant funding must be governed by the normal standards and procedures of (as applicable) the LRO or Co-Investigator and must be covered by the formal audit arrangements that exist in the (as applicable) LRO or Co-Investigator. The Foundation reserves the right, at its discretion and expense, to commission an audit of the expenditure of Grant funding and/or systems used by the (as applicable) LRO or Co-Investigator to administer the Grant funding.

5.7 The (as applicable) LRO or Co-Investigator must maintain a separate accounting record specific to the Grant and all costs and expenditure properly incurred by that organisation relating to the Grant should be accounted for through that record.

5.8 The Foundation reserves the right to have reasonable access to inspect the records and financial procedures associated with the Grant or to appoint any other body or individual for the purpose of such inspection. The (as applicable) LRO or Co-Investigator 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 Grant Terms and Conditions.

6. Protection and Exploitation

6.1 As a charity funded by donations from the general public, the Foundation is under an obligation to ensure that useful results of research that it funds (including the Results) are applied for the public good.

6.2 It is the responsibility of the LRO and all engaged in the Research, to make every reasonable effort to ensure that the Results, whether protected by Intellectual Property rights or not, are used to the benefit of society and with the ultimate aim of improving human health.

6.3 LRO must promptly respond to requests to provide the Foundation with assurance that appropriate systems and capabilities are in place to protect and manage exploitation of the Results. The LRO will ensure that Principal Investigator promptly responds to requests from the Foundation for information about exploitation outputs and outcomes from the Research.

6.4 Unless stated otherwise, the ownership of all Results, and responsibility for their protection and exploitation, rests with the organisation(s) whose Investigators generate them. Where the Grant is associated with the LRO and one or more Co-Investigators and/or Collaborators, the basis of collaboration between these organisations, including ownership of Results and rights to protect and exploit the same, is expected to be set out in (a) formal collaboration agreement(s). It is the responsibility of the LRO to put such (an) agreement(s) in place before the Research begins. The terms of collaboration agreement(s) must not conflict with the Grant Terms and Conditions and shall specify which organisation has the primary responsibility for the protection and exploitation of certain/all Results as the Exploiting Party. Following any request from the Foundation and solely for the purposes of enabling the Foundation to confirm compliance with this Section 6.4, the LRO shall promptly provide the Foundation with a copy of any such formal collaboration and/or other agreements concluded with Co-Investigators and/or Collaborators in respect of the Research. The Foundation shall maintain any agreements it receives pursuant to this Section 6.4 in confidence and shall only disclose it to its trustees, employees and professional advisors that are bound by suitable obligations of confidence.

6.5 Following the identification of any Results that may be of medical or commercial value, the LRO will notify the Foundation immediately giving details of: (i) the nature of the Results at issue, (ii) the steps taken or proposed to be taken to protect the Intellectual Property therein, (iii) as applicable, an initial view of the potential Commercial Exploitation of the Results and/or reasonable details of the proposed Commercial Exploitation of the Results (including a copy of any proposed agreement/s covering the same), and (iv) notice of whether the LRO (either directly or via its Technology transfer Group, TTG) or a Co-Investigator (either directly or via its TTG) or a Collaborator (either directly or via its TTG) wishes to obtain the Foundation's consent to undertake the Commercial Exploitation of such Results as the Exploiting Party. The Foundation shall maintain any information it receives pursuant to this Section 6.5 in confidence and shall only disclose it to its trustees, employees and professional advisors that are bound by suitable obligations of confidence.

6.6 The Exploiting Party must obtain the Foundation's consent prior to undertaking the Commercial Exploitation of Results. The Foundation shall not withhold or delay such consent in circumstances where it believes the proposed Commercial Exploitation is an appropriate means of achieving public good. As a condition of granting such consent, the Foundation will require that the Exploiting Party agrees to enter into a revenue sharing agreement with the Foundation, which shall be based on the following:

a) The Exploiting Party shall first determine if:

(1) the Grant (together with other Foundation funds) is the sole source of funding for generation of Results to be Commercially Exploited, in which case the revenue share set out in 6.6 (b) below shall apply to the total Net Revenue; or

(2) the Grant (together with other Foundation funds) is not the sole source of funding for generation of Results to be Commercially Exploited, in which case the Net Revenue shall be pro-rata calculated to take into account: (a) the inventive contribution of each Investigator; followed by (b) the proportionate funding contributions of the Foundation and other third party funders of each Investigator as appropriate (such funding contribution to exclude any salary support provided by the LRO, Co-Investigator and/or Collaborator from its internal funding, as well as any overhead or other indirect costs including for the avoidance of doubt Higher Education Funding Council for England, or Wales or Scottish Funding Council, or Department for the Economy of Northern Ireland funding); and the revenue-sharing formulae set out in Section 6.6 (b) below shall then apply to the portions of Net Revenue attributed to the Foundation's contribution.

b) The Exploiting Party shall share fifty percent (50%) of Net Revenue with the Foundation.

6.7 Where the granting of rights for Commercial Exploitation of Results entitles the Exploiting Party to take

Equity, the Equity shall be shared between the Foundation and the Exploiting Party in accordance with the calculations used for the sharing of Net Revenue set out in Section 6.6. The Foundation may elect at its sole discretion: (i) to hold such Equity in its own name (or the name of its nominee), (ii) to have the Exploiting Party hold such Equity for the benefit of the Foundation, or (iii) for sums received by the Exploiting Party which derive from the Equity (such as from dividends, sale or other disposal) to be shared with the Foundation in accordance with Section 6.6.

6.8 Arrangements with Co-Investigators/Collaborators and/or arrangements for Commercial Exploitation must not prevent: (i) use of the Results in future academic/non-commercial research; or (ii) the dissemination of the Results in accordance with academic custom and practice. A temporary/time-limited delay in publication of Results is acceptable in order to allow for the protection of Intellectual Property in such Results and/or to allow arrangements to be established with (as applicable) Co-Investigators and/or Collaborators for the exploitation of jointly owned Results.

6.9 The Foundation may, in individual cases, reserve the right to retain ownership of certain Results (or assign it to a third party under an exploitation agreement) and to arrange for Commercial Exploitation of such Results for the public benefit. This right, if exercised, will be set out in an additional condition of the Grant Award Letter. In such a situation, the Foundation shall be deemed to be the Exploiting Party and Section 6.13 shall apply.

6.10 The Foundation agrees there should be suitable recognition and reward to the Investigators who undertake activities that deliver commercially exploitable Results. The LRO, Co-Investigators and Collaborators are responsible for the payment of such reward to their respective Investigators from their own share of Net Revenue (i.e. after deduction of the Foundation's share of Net Revenue). The LRO must ensure such arrangements are consistent with these Grant Terms and Conditions and that all those associated with the Research are aware of, and accept, these arrangements.

6.11 If the (as applicable) LRO (or its TTG), the Co-Investigator (or its TTG), the Collaborator (or its TTG) or other organisation appointed as the Exploiting Party does not protect and/or exploit the corresponding Results to the Foundation's satisfaction, the Foundation shall have the right, but not the duty, to protect and exploit such Intellectual Property as the Exploiting Party. The LRO agrees to undertake and will ensure that (as applicable) the Co-Investigator(s) and/or Collaborator(s) (and its/their respective Investigators and TTG) undertake, all acts required to assist the Foundation in such protection and exploitation.

6.12 Should the (as applicable) LRO (or its TTG), Co-Investigator (or its TTG) and/or a Collaborator (or its TTG) or other organisation appointed as the Exploiting Party decide to not to seek patent or like protection in respect of any Results or to withdraw or allow patent or like protection to lapse, the Foundation shall be entitled to: (a) take assignment of the Results concerned and become the Exploiting Party in respect of such Results; and (b) unless prevented by pre-existing third party rights, obtain a non-exclusive sublicensable licence to any other Intellectual Property rights of the (as applicable) LRO, Co-Investigator(s) and/or Collaborator(s), necessary to do all acts necessary for the Commercial Exploitation of said Results. The LRO shall give (or shall ensure that its TTG and/or the Co-Investigator or its TTG and/or the Collaborator or its TTG and/or other organisation appointed as the Exploiting Party gives) the Foundation sufficient notice and all assistance reasonably necessary to allow it to do so effectively.

6.13 Where the Foundation is the Exploiting Party, it shall enter into a revenue sharing agreement with (as applicable) the LRO or its TTG and share Net Revenue with the LRO in accordance with the calculations set out above and the (as applicable) the LRO or its TTG shall be responsible for sharing such revenues with the Co-Investigators, Collaborators and/or Investigators as may be appropriate.

6.14 Upon reasonable request by the Foundation, and at least once per annum, the LRO shall ensure the Exploiting Party provides the Foundation with a written report setting out in reasonable detail:

a) where the Exploiting Party has not granted a third party the exclusive right to undertake the Commercial Exploitation of the Results, the plans and progress which the Exploiting Party has made in respect of achieving the Commercial Exploitation of such Results;

b) where the Exploiting Party has granted: (i) third party(ies) non-exclusive/exclusive rights to undertake the Commercial Exploitation of the Results , the name(s) of such third party(ies) and the plans and progress which said third party(ies) has(have) made in respect of the Commercial Exploitation of such Results ; and

c) a non-confidential summary of the information Section 6.14 (a) and/or 6.14 (b), which allows the Foundation to evaluate the societal benefits (including but not limited to improving human health) generated from such activities and which the Foundation can publish on its web-site and otherwise share publicly.

6.15 The Foundation shall maintain any information it receives pursuant to Section 6.14 (a) and/or 6.14 (b) in confidence and shall only disclose it to its trustees, employees and professional advisors that are bound by suitable obligations of confidence.

6.16 The Foundation will have the right to audit the relevant accounts of the Exploiting Party to confirm that there has been an appropriate calculation and sharing of Net Revenues, made in relation to any such Commercial Exploitation.

6.17 The LRO hereby grants, and shall procure that each of its Co-Investigators and Collaborators grant, to the Foundation a non-exclusive, sub-licensable, worldwide, perpetual, irrevocable, royalty-free licence to use the Results for its charitable purposes (including use for non-commercial research and for promotional/publicity purposes in furtherance of the Foundation's fundraising and other charitable purposes), subject to any reasonable confidentiality requirements that the (as applicable) LRO, Co-Investigators and/or Collaborators may reasonably require: (i) prior to the filing of patent or other applications for the protection of the Intellectual Property in the Results; and/or (ii) during the preparation and submission of manuscripts reporting the Results for publication.

6.18 For the avoidance of doubt, the LRO shall not be relieved of any of its obligations under the Grant Terms and Conditions if any of the Results are commercially exploited by the Co-Investigators, Collaborators or their respective TTGs. The LRO shall procure that each such Co-Investigator and Collaborator and their respective TTGs comply with the provisions of this Section 6 and references to (as applicable) the LRO, Co-Investigator and/or Collaborator shall be deemed to include a reference to the respective TTG.

7. Reporting on the outcomes of Research

General

7.1 The Foundation collects information on the outputs and outcomes of its funding. The LRO must ensure the Principal Investigator submits Research outcomes data annually, within a specified submission period, to the Foundation's online reporting system (currently Researchfish). The Foundation also requires the Principal Investigator to submit a final annual report on the Research to the Foundation's online reporting system (currently Researchfish) within 3 months of the end of the Grant.

7.2 Interim reports may be required and the Principal Investigator will be notified of these as necessary. The LRO must ensure the Principal Investigator submits the required interim report within three months of receiving such request.

7.3 The Foundation also requires submission of a separate final scientific report (Final Scientific Report) at the end of the Research. The LRO must ensure the Principal Investigator submits the required Final Scientific Report within three months of the end of the Grant and on the form provided. The Foundation will not release final payment of the Grant until after the Final Scientific Report is received in a form acceptable to the Foundation.

7.4 The Foundation expects full compliance with interim, annual and final reporting requirements set out in this Section 7; the LRO must ensure that the required reports and information is provided in accordance with this Section 7 and the guidance/forms provided by the Foundation.

Reporting and Sanctions

7.5 The Foundation reserves the right to impose financial sanctions where it identifies areas of non-compliance to the Grant Terms and Conditions.

7.6 If a Final Scientific Report or the FES is not received within three months of the end date of the Grant, the final invoice will not be paid until this information is received. All payments made throughout the Grant may be recovered if the Final Scientific Report and/or FES is not received within 6 months of the end of the Grant.

8. Publications and Publicity

Publications and acknowledgement of support

8.1 The LRO must ensure the Principal Investigator and/or the Co-Investigators and/or other Investigators, subject to the procedures laid down by (as applicable) the LRO, Co-Investigators and/or Collaborators, publishes and/or otherwise publicly presents the Results in accordance with normal academic practice and our policy on Open Access: https://www.medicalresearchfoundation.org.uk/uploads/Medical-Research-Foundation-Open-Access-Policy.pdf. It is a condition of our grants that all publications that arise must be archived and be immediately available through Europe PubMed Central (Europe PMC), under a Creative Commons Attribution (CC BY) public copyright licence.

8.2 The LRO shall ensure the support received from the Foundation is acknowledged (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 Research or otherwise report the Results. Without limiting Section 8.3, the Research and the Results should formally be described as "funded by a grant from the Medical Research Foundation".

8.3 The LRO must ensure the Principal Investigator contacts the Foundation before the PI or any other Investigators make any public announcements regarding the Research or the Results.

8.4 Publications in scientific/medical journals reporting the Results should acknowledge the funding source using the journal's standard format and with the Foundation's full name stated, and the Grant Reference number where possible. For clarity, Grant funds may be used to cover the costs of such publications. At the time the Application was accepted for funding, The Principal Investigator provided a non-confidential publishable abstract about the proposed Research. The LRO acknowledges and agrees such abstract may be published on Foundation's website. The LRO further acknowledges and agrees that the Foundation will aim to publicise the Grant and that the Foundation will consult with the Principal Investigator and the LRO when preparing any publicity material required for that purpose.

Participation in fundraising activities

8.5 The LRO acknowledges and agrees the Foundation may use data or other material on the Research that it receives in accordance with the Grant Terms and Conditions for fundraising or publicity purposes. The Foundation agrees to consult with the PI before publicly disclosing such information/data in order to ensure publication or protection of the IP is not jeopardized.

8.6 The LRO shall ensure the Principal Investigator helps promote the Foundation and its charitable aims by complying with all reasonable requests in relation to the Foundation's publicity, research engagement and fund-raising, including requests to attend or speak at events and provide help with images and copy for publications.

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

8.8 The LRO must comply with, and must ensure the Co-Investigators, Collaborators and Investigators must comply with, any guidelines provided by the Foundation for branding, communications and other public engagement in relation to the Research.

8.9 The LRO must ensure the Principal Investigator and Co-Investigators actively communicate details of the Research (including the Results) 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.

Gifts

8.10 The Foundation shall have absolute right of any legacy, donation or gift to or in the name of, the Foundation or the Medical Research Council, irrespective of whether such legacy, donation or gift could be construed to have arisen from publication of the Results or the participation of the LRO, Collaborators and/or Investigators in any activity set out in Section 8 , and such right shall extend beyond the term of the Grant without time limitation.

9. Data protection

9.1 The Foundation will use personal information provided in connection with the Grant, including in the Application and in any interim and final report, for: (i) processing the Application, (ii) implementing and monitoring the Grant, including processing and payment of any consequential funding, (iii) monitoring and reviewing the Research, Results and Commercial Exploitation in accordance with the Grant Terms and Conditions, and (iv) maintenance and review of Foundation funds. This may include but is not limited to:

- 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; and
- Policy and strategy studies.

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

9.3 All personal data submitted to or otherwise collected by the Foundation in the Application or during the Grant will be handled in accordance with Data Protection Regulations.

10. Disclaimer

10.1 The Foundation accepts no liability, financial or otherwise, for expenditure or liability arising from the Research or from the use and/or Commercial Exploitation of Results, except as set out in the Grant Terms and Conditions, or otherwise agreed in writing.

10.2 The Foundation will not indemnify the LRO, Co-Investigator(s), Collaborator(s), any Investigator(s) or any other person working on the Research against any claims for compensation or against any other claims (whether under any stature of regulation or a common law) for which (as applicable) the LRO, Co-Investigator, Collaborator, Investigator or other person may be liable as an employer or otherwise for which any such person may be liable.

10.3 Where any part of the Research is 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.

10.4 The Foundation reserves the right to terminate the Grant at any time, subject to reasonable notice and to any payment that may be necessary to cover outstanding and unavoidable commitments incurred before the date of such notice.

10.5 Irrespective of whether the Grant continues until end of the period shown in Grant Award Letter or is terminated early and/or is otherwise reduced in value, no liability for payment or redundancy or any other compensatory payment for the dismissal of staff funded (whether in whole or in part) by the Grant will be accepted, but, negotiations will be held between the Foundation and the LRO with regard to: (i) other contractual commitments affected by such early termination or reduction in value; and (ii) concerning the disposal of assets acquired under the Grant.

11. Status

11.1 The Grant Terms and Conditions will be governed by the laws of England and Wales; all matters relating to the Grant Terms and Conditions will be subject to the exclusive jurisdiction of the courts of England and Wales. If any provision of the Grant 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.

11.2 These terms and conditions, together with any additional conditions set out in the Grant Award Letter; contain the whole agreement between the Foundation and the LRO in relation to the stated Grant. In the event of any conflict between these terms and conditions and any additional terms and conditions set out in the Grant Award Letter, the latter shall prevail. In the event of any conflict between the Application and the Grant Terms and Conditions, the latter will prevail.

11.3 The Foundation and the LRO do not intend that any of the Grant Terms and Conditions should be enforceable by any third party.

11.4 The Foundation reserves the right to vary these terms and conditions from time-to-time by posting such variation on its website.