

ME RESEARCH UK

Funding Conditions 2018

ME Research UK

Adopted by the Board of Charity Trustees on 25th April 2018

Chairman of Board of Charity Trustees

ME Research UK

Version 8.2

Authorised by: The Board of Charity Trustees

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ME Research UK Funding Conditions

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These Grant Conditions, together with the Grant Award Letter (GAL) and the Funding Policies, set out the terms and conditions on which the Grant is made by ME Research UK to the Host Institution and Grant Holder. Funding Policies are available on the ME Research UK website.

1 DEFINITIONS

1.1 ME Research UK

ME Research UK - a Scottish Charitable Incorporated Organisation No SCO 36942 whose registered address is The Gateway, North Methven Street, Perth, PH1 5PP, UK

1.2 Directly Allocated Costs

The cost of resources used by a project which are shared by other activities. They are charged to projects on the basis of estimates rather than actual costs and do not represent actual costs on a project by project basis e.g. electricity, water.

1.3 Direct Costs

The costs explicitly identifiable as arising from the conduct of a project.

1.4 Equipment

The equipment required to conduct the Research which costs £2,000 or more.

1.5 Funded Intellectual Property

All Results.

1.6 Funded Materials

Biological and chemical materials comprised in Funded Intellectual Property.

1.7 Grant

The funding made pursuant to and described in the Grant Award Letter.

1.8 Grant Award Letter (GAL)

The letter from ME Research UK to the principal Grant Holder confirming the award of the grant and also specifying the amount of the Grant.

1.9 Grant Conditions

The conditions set out in this document.

1.10 Grant Holder(s)

The lead applicant, any joint applicant as specified in the Grant Award Letter or any persons to whom the Host Institution allocated the Grant or any part thereof.

1.11 Grant Period

The period of the grant set out in the Grant Award Letter.

1.12 Host Institution

The university, institution or other body at which some or all of the research funded by the Grant will be carried out.

1.13 Human Biological Samples

Tissue, blood and other biological samples taken from human beings.

1.14 Indirect Costs

Non-specific costs charged across all projects based on estimates that are not otherwise included as Directly Allocated Costs. They include the costs of the Host Institution's administration such as human resources, finance, library and departmental services.

1.15 Instalment

The portion of the award value committed over a defined period, the instalment period. Subsequent instalment(s) of the award are pending successful interim reviews.

1.16 NHS Number

An NHS number is a national unique patient identifier which is used by healthcare staff and service providers to match an individual to their health records. Everyone registered with the NHS has their own unique number.

1.17 NIHR CRN Portfolio

A database of clinical research studies that are supported by the National Institute of Health Research Clinical Research Network in England.

1.18 Premises

All research facilities where the Research is conducted.

1.19 Research

The research and investigation which is the subject of the Grant.

1.20 Research Personnel

The Grant Holder and the person(s) working under his/her supervision (including students, visitors and sub-contractors).

1.21 Results

All inventions, discoveries, materials (including biological and chemical materials), technologies, products, data, algorithms, software, patents, databases, copyright, other intellectual property and know-how arising from Research.

1.22 Studentship

A grant to provide the stipend and other costs associated with a non-clinical PhD student.

1.23 Technology Transfer Agreement (TTA)

Unless ME Research UK determines otherwise, a framework agreement governing the management and exploitation of Results as well as results of all other research funded by ME Research UK at the Host Institution from time to time.

2 GENERAL CONDITIONS

2.1 General Obligation

ME Research UK expects that the grant holder(s) will complete the project within the agreed period and the overall grant awarded and will make no material change to the description of the project without prior approval of ME Research UK.

2.2 Original Application

ME Research UK has placed reliance on the application and related information provided to ME Research UK by the recipient in connection with the project being true, accurate and complete in all material respects and not omitting any fact or circumstances that might make such information misleading. The recipient must inform ME Research UK at the earliest opportunity if any fact or circumstance should arise that would make the information misleading.

2.3 Basic Understanding

The grant is made on the basis of ME Research UK's understanding of the project. Any proposals to use grant monies for projects or purposes other than the project specified in the Award Letter or any other change in the nature, structure and format of the project (including the results), will require the prior written agreement of ME Research UK. Such agreement may be refused at the absolute discretion of ME Research UK.

2.4 Commencement

If the project does not commence within 6 months of the offer by ME Research UK, ME Research UK reserves the right to withdraw the offer.

2.5 Cost Limitations

ME Research UK will not pay for staff travel expenses, advertising for posts, secretarial work, stationery or contribution to general departmental overheads.

2.6 Responsibility

The recipient must accept full responsibility for the management, monitoring and control of the project and for any participants engaged in carrying it out and for any payments due to them.

2.7 Liability

Save as specified to the contrary in this document, ME Research UK accepts no responsibility or liability, financially or otherwise, for any loss, claim, damage or expense arising out of or in connection with the project.

3 RESPONSIBILITIES IN RESEARCH PRACTICE

3.1 Employment

3.1.1

ME Research UK does not act as an employer with respect to the Grant, and therefore, in all cases where support is provided by the Grant for the employment of staff, the Host Institution or its permitted subcontractor(s) must issue a contract of employment for such staff in compliance with the relevant laws and regulations.

In exceptional and specific circumstances, a Grant may include support costs for ME Research UK staff working within the Host Institution. Such staff will remain ME Research UK employees.

3.1.2

All clinical staff appointed on grants should hold honorary NHS clinical contracts or honorary university contracts at the appropriate level. The Host Institution is responsible for ensuring all clinical staff possess the necessary professional registration and occupational health clearance. ME Research UK accepts no liability for any claim arising out of matters relating to fitness of practice.

3.1.3

ME Research UK will not be responsible for, nor will it indemnify the Host Institution against, any claim for redundancy, compensation, dismissal or discrimination or any other claims for which the Host Institution or any permitted sub-contractor may be liable as an employer or otherwise.

3.1.4

The Host Institution must ensure that all permanent and temporary staff and students employed or involved in the work funded by the Grant receive training appropriate to their duties, in accordance with any applicable legal or regulatory requirements. This includes management and leadership training and development for all ME Research UK supported staff with managerial responsibilities.

3.1.5

The Host Institution must ensure that appropriate Premises are available to house the Research Personnel and all equipment used in the Research is fully maintained, kept in an appropriate and safe state of repair and properly serviced for the duration of the Grant. The Host Institution must comply with and perform all obligations and duties at law (including all health and safety legislation) in respect of the Premises.

3.1.6

The Host Institution must identify any risks which could affect the health of new and expectant mothers and must take any actions necessary as a result of the risk assessment.

3.1.7

Researchers in receipt of salary support from ME Research UK must ensure that their time commitments to commercial organisations and other non-research activities are compatible with the policies of the institution and any conditions in the Grant Award Letter.

3.1.8

ME Research UK funded researchers must disclose to their institutions (a) benefits in cash in excess of £10,000 per annum or (b) benefits in equity of any level, received either as compensation for work undertaken for a commercial organisation, or in consideration of the transfer of intellectual property.

3.1.9

In managing a perceived or actual conflict of interest, the institution must use all reasonable endeavours to ensure that ME Research UK is not put at risk of being in breach of charity law or regulation because of the relationship of a ME Research UK funded researcher with a commercial organisation. In particular, the institution should act to ensure that the useful results of ME Research UK funded research are applied for the public benefit, with only incidental private benefit. This might involve requiring a ME Research UK funded researcher to relinquish direct control over some, or all, of the assets they hold in a commercial organisation or requiring the level of compensation offered to the ME Research UK funded researcher to be capped.

3.2 Project Management

3.2.1

It is the responsibility of the Host Institution and Grant Holder to ensure that all parties, including collaborators, supervisors, and staff employed on ME Research UK grants comply with the terms and conditions.

3.2.2

The Host Institution must hold appropriate policies of insurance covering personal indemnity, public liability, and employer's liability and shall maintain such insurance policies throughout the Project and any commercialisation of the Results.

3.2.3

The Host Institution must ensure proper financial management of grants and accountability for the use of public funds.

3.2.4

The Host Institution must ensure that the Grant is used for the purposes for which it was awarded. Any plan to diverge from the aims outlined in the original grant application requires prior written agreement from ME Research UK. In the event the research is terminated early, ME Research UK must be notified in writing.

3.2.5

The Host Institution must ensure that adequate resources are provided to support the activities and timeframe described in the GAL.

3.2.6

The Host Institution must notify ME Research UK if there is any change in status, or of Research Personnel, that may affect its eligibility to hold the grant.

3.2.7

The Host Institution will inform ME Research UK promptly of any pre-existing arrangements which may lead to a breach of the Grant Conditions. The Host Institution shall not enter into, or permit any person involved with the project to enter into, consultancies, third party restrictions or arrangements which may affect the Research without the prior written agreement of ME Research UK.

3.2.8

The Host Institution and the Grant Holder must notify any commercial collaborators of the application and obtain their agreement for the disclosure of confidential information.

3.2.9

ME Research UK must be notified of any potential new treatment arising from a ME Research UK Grant.

3.2.10

ME Research UK acknowledges that the Host Institution is subject to the Freedom of Information Act 2000. If the Host Institution receives a 'Request for Information' in respect to any part of the Grant, the Host Institution must notify and consult with ME Research UK on the response to the request.

3.3 Scientific Conduct

3.3.1

ME Research UK reserves the right to investigate any aspect of fraud or misconduct itself as it reasonably sees fit and the Host Institution shall provide assistance and information to ME Research UK for that purpose.

3.3.2

The Host Institution is responsible for managing conflicts of interests ensuring:

- i. Any relationship between the Host Institution, Researchers and commercial organisations shall be appropriate and not unduly benefit the commercial organisation or influence the research
- ii. Any form of remuneration by a company for consultancy shall be made only for the appropriate provision of advice and the exchange of ideas and shall not enable that organisation to gain inappropriate access to Funded Intellectual Property

iii. ME Research UK is notified of any conflicts which may be relevant to the research.

3.4 Good Scientific Practice

3.4.1

ME Research UK requires the highest standards of integrity to be adhered to by the researchers whom it funds with the Grant. The Host Institution must have in place its own published standards of good research practice and formal written procedures for the investigation of allegations of scientific misconduct and shall make those available to ME Research UK on request. Such standards must take into account the Association of Medical Research Charities' 'Guidelines on Good Research Practice'. The procedure(s) must also include guidance or a code of practice on standards of professional behaviour, provisions for induction and training of staff, monitoring, resolutions and procedures for handling allegations and fair procedures and appropriate protection for both the accused and any 'whistle-blower'.

3.4.2

The Host Institution must ensure that before the research funded by the Grant commences and during the full Grant Period, all the necessary legal and regulatory requirements, including any necessary or appropriate ethical approval, in order to conduct the research are met. This includes obtaining all licences and approvals. The Host Institution accepts full responsibility for ensuring that any such approvals are in place at all relevant periods of the Grant.

3.4.3

It is the responsibility of the Host Institution to inform ME Research UK, in confidence, at the earliest opportunity, about allegations, progress of the investigation and the investigation outcome of research misconduct that concern Researchers.

3.4.4

In the event of any investigation of scientific misconduct, both during or after the Grant period, involving research or researchers funded by the Grant then ME Research UK must be informed within 7 days of the Host Institution initiating any such investigation of scientific misconduct. ME Research UK reserves the right to suspend the Grant in the event of any suspension of staff paid from the Grant while the investigations are on-going.

3.4.5

ME Research UK must be informed immediately of the outcome and reserves the right to take any further action it may feel appropriate, including termination of the Grant with immediate effect.

3.4.6

If publications have been produced where academic fraud has been established, the Host Institution must ensure that appropriate errata and/or retractions are promptly published and that ME Research UK is notified promptly of all such actions.

3.4.7

The Host Institution must ensure that before the research funded by the Grant commences and during the full Grant Period, all the necessary legal and regulatory requirements, including any necessary or appropriate ethical approval, in order to conduct the research are met. This includes obtaining all licences and approvals. The Host Institution accepts full responsibility for ensuring that any such approvals are in place at all relevant periods of the Grant.

3.4.8

Grant Holders are expected to respond positively and punctually to requests to referee ME RESEARCH UK grant applications.

4 GRANT ADMINISTRATION

4.1 Grant Award

4.1.1

ME Research UK does not pay directly allocated costs unless specifically and clearly identified in the Grant Award Letter. ME Research UK does not pay any indirect costs.

4.1.2

All amounts specified in the Grant Award Letter are inclusive of Value Added Tax (VAT).

4.1.3

Once an application for financial support has been approved, a grant will only be awarded when ME Research UK is satisfied that all the necessary conditions have been met.

4.1.4

Once ME Research UK has established the level of award for the first year, a fixed indexation rate may be applied to all subsequent years of the award for salaries and running expenses. If applicable, such indexation will be disclosed in the Grant Award Letter.

4.1.5

The Host Institution will be responsible for any expenditure on the Grant in excess of the funding stipulated in the Grant Award Letter.

4.1.6

The Host Institution, Head of Department and proposed Grant Holder must formally accept the Award as detailed in the Grant Award Letter and agree to the terms and conditions.

4.1.7

The Grant must be activated by the Grant Holder within three (3) months from the start date indicated on the Grant Award Letter. Any delay to the start date must be approved by ME Research UK.

4.1.8

The Grant termination date is defined by the duration of the award from the activation date.

4.1.9

ME Research UK shall be permitted to disclose information regarding the award to relevant regulatory authorities, Higher Education Funding Councils and other agencies administering governmental funding.

4.2 Grant Management

4.2.1

Payments for recurrent costs (where applicable and disclosed in the Grant Award Letter) will normally be made quarterly in arrears.

4.2.2

For joint awards where the research will be split between two or more institutions, the designated Host Institution shall receive all payments made by ME Research UK. The designated Host Institution must transfer appropriate funds to other participating institutions without undue delay.

4.2.3

ME Research UK will only pay travel costs for patients and volunteers as specified in the GAL. ME Research UK will not pay for participation costs for patients and volunteers, including prizes or gift vouchers for participation.

4.2.4

Trials supported by ME Research UK should be entered into the NIHR CRN portfolio by the Grant Holder and be eligible for NIHR CRN support. The Grant Holder is responsible for ensuring that up-to-date trial information including recruitment data are submitted monthly through the designated Accrual Data Contact (ADC).

4.2.5

The NHS number (or equivalent in the devolved UK health departments) must be recorded for all patients entering clinical trials supported by ME Research UK. The collection of NHS number is strongly encouraged in trials of healthy volunteers.

4.3 Grant Management - Salary Allocation

4.3.1

Salary allocation may be used to fund salary, the employer's national insurance contribution, and an employer's pension contribution which will not be higher than the rate used by the USS or NHS scheme. It must not be used to offset any prior under funding of the pension scheme.

4.3.2

Salary allocation may not be used for any bonus or merit awards.

4.3.3

All advertisements for staff that will be funded by a grant must indicate that the research is funded by ME Research UK. The Host Institution is responsible for advertising posts and must meet recruitment-associated costs.

4.3.4

The Host Institution may use the salary allocation to make maternity, paternity, adoption, or sick leave benefit payments to staff whose salaries are paid from a grant funded by ME Research UK, provided the period of leave does not extend beyond the termination date of the grant and that the staff member has been employed on the contract for the statutory requirement. All benefit payments must be taken from the salary allocation for the post must be net of any benefit payments recoverable elsewhere and must not exceed the amount awarded.

4.3.5

The Host Institution may use the salary allocation to pay holiday in lieu.

4.3.6

The Grant Holder must notify ME Research UK when the situation for long term leave arises. Any unspent salary allocation for the post after long term leave has been paid may be used to employ temporary cover.

4.4 Grant Management - Virement

4.4.1

ME Research UK will allow the allocations for salary and running expenses to be openly vired to other salary and running expenses allocations. The following conditions apply:

- i. The allocation must only be utilised on costs that meet the conditions of award. The only exceptions to this are unspent allocation may be used to pay for costs of attendance and standard class travel for Research Personnel to conferences related to the research and for open access publication fees.

ii. Virements are not allowed:

- . to or from the amount allocated for University studentship fees
- . to or from the amount allocated for a Principal Investigator's Salary
- . from the salary of any post unfilled for six (6) or more months
- . to or from the amount allocated for Equipment

4.4.2

All virements must be declared at each financial reconciliation. For Grants where salary and running expenses are not specifically allocated, details on how the funds were allocated will be required at each financial reconciliation.

4.5 Grant Management – Financial Reconciliations

4.5.1

Host Institutions must submit a final reconciliation at the end of the Grant. ME RESEARCH UK reserves the right to process reconciliations as it reasonably sees fit if the Host Institution does not respond to reconciliation queries within a calendar month.

4.5.2

ME Research UK reserves the right to recover any unspent funds at the end of each reconciliation period.

4.5.3

Where any amounts paid by ME Research UK exceed the amounts justified or the Grant has not been used in accordance with the terms and conditions of award, ME Research UK will recover the sum in question on whatever terms it may specify. ME Research UK may recover sums owed to it by offsetting them against any other sums (including grant payments) owed to the Host Institution.

4.5.4

At the end of each instalment period, the Grant Holder is required to submit a scientific report. Continued support for the award will only occur if the funding committee deems satisfactory progress has been made, to an appropriate standard of research, and in compliance with the terms and conditions of award.

4.5.5

A final report must be submitted within three (3) months of the end of the Grant end date.

4.5.6

The final instalment of a grant will not be paid until all prior instalments of the grant have been reconciled and the final report has been received.

4.5.7

At the request of ME Research UK, the Host Institution and/or its external auditors shall provide written confirmation that the Grant has been used for the purpose for which it was awarded and that the costs incurred meet the conditions of the Grant. On request, the Host Institution shall also make the necessary arrangements to enable ME Research UK and its agents to visit the Host Institution to discuss the administration and accounting of its awards and, if necessary, to conduct its own audit of any ME Research UK grant account at the Host Institution or the activities funded. For this purpose, ME Research UK and its agents and advisors may inspect and take copies of all relevant books of accounts and records. Where

elements of expenditure under the Grant have been subcontracted, the Host Institution should ensure that the right of access extends to the accounts, records, equipment and facilities of any such subcontractor relevant to the management of the Grant.

5 Grant.

5.1 Grant Management – Equipment

5.1.1

Funds for equipment are awarded on the condition that only those items specified on the Grant Award Letter may be purchased.

5.1.2

The Host Institution must ensure that it has in place clearly defined procedures for the procurement of equipment and that equipment funded by the Grant is acquired by the Host Institution in accordance with these procedures. ME Research UK will not accept any liability to pay VAT due to any failure of the Host Institution to claim relief on qualifying equipment.

5.1.3

Equipment purchased through a ME Research UK grant is awarded to the Host Institution specifically for the purpose of the Grant Holder's research. The equipment must be used primarily for the approved research project during the lifetime of the Grant.

5.1.4

ME Research UK will not pay any access charges for use of equipment funded by a ME Research UK grant.

5.1.5

The Host Institution must ensure that the equipment funded by the Grant is appropriately insured and maintained throughout its useful life. ME Research UK will meet any agreed maintenance costs for awarded equipment for the period of the Grant.

5.1.6

If any equipment funded under the Grant is lost, damaged or destroyed during the life of the Grant, the Host Institution will be required to repair or replace it at its cost.

5.1.7

An equipment award must be claimed within the relevant year specified in the Grant Award Letter. The equipment must be of the same type from that awarded and copies of relevant invoices must be provided to process the claim.

5.2 Grant Management – Transfer

5.2.1

If a Grant Holder would like to transfer the Grant to another Institution, and the Institution agrees, or the current Grant Holder/Host Institution would like to transfer the award to a new Grant Holder, any such transfer will be subject to prior written approval from ME Research UK. Transfers are only permitted to Institutions within the UK which are eligible to receive funding from ME Research UK and are able to demonstrate to ME Research UK's satisfaction the ability to support the Research during the tenure of the grant. The new Host Institution/Grant Holder must agree to abide by the Terms and Conditions of award.

5.2.2

If the Grant Holder transfers to another institution during the Grant Period, ME Research UK reserves the right to require that the equipment funded by the Grant is transferred with him/her.

6 WITHHOLDING OF GRANT

6.1 Breach of Standards

If the Grant Holder or the Host Institution has failed to comply with these Conditions, ME Research UK's policies or the norms of scientific research standards then ME Research UK may withhold payment of any instalment of the Grant until the non-compliance is remedied to ME Research UK's reasonable satisfaction.

7 REPAYMENT OF GRANT

7.1 Breach of Conditions

ME Research UK may by written notice to the Host Institution demand within 21 days repayment of the Grant made to the extent of that part of the Grant (if any) which:

- i. has not been applied for the Grant purposes stated in the Grant Award Letter; or
- ii. has been spent on items of expenditure not allowed by the Grant Award Letter; or
- iii. has been paid by ME Research UK for items of expenditure which have also been funded directly by a third party other than the Host Institution.

8 INTELLECTUAL PROPERTY

8.1 Funded Intellectual Property

8.1.1

Funded Intellectual Property shall, in the first instance, vest in the Host Institution. The Host Institution shall ensure that the contracts of employment or other terms of engagement of its Research Personnel provide for automatic and immediate vesting in the Host Institution of Funded Intellectual Property.

8.1.2

The Host Institution and its Research Personnel shall co-operate fully with ME Research UK in all matters relating to Funded Intellectual Property.

8.1.3

Following receipt of a request by ME Research UK, the Host Institution will negotiate and enter into a TTA with ME Research UK in relation to Funded Intellectual Property.

8.1.4

In the event that there is a TTA in place between ME Research UK and the Host Institution, the terms of such TTA shall supersede this Section 8 from the date such agreement becomes effective.

8.1.5

In the event that there is no TTA in place the Host Institution agrees to the following additional grant conditions (8.1.6-8.1.15):

8.1.6

The Host Institution grants ME Research UK the non-exclusive right itself, or by granting to recipients of ME Research UK funding the right, to use Funded Intellectual Property for the purposes of non-commercial research whether alone or in collaboration with third parties and whether sponsored or funded, in whole or in part, by any third party including any commercial entity.

8.1.7

The Host Institution shall allow ME Research UK to visit its premises and to liaise freely and at will with its Research Personnel for the purpose of identifying Funded Intellectual Property. In addition, promptly following the identification by the Host Institution (or its agent) of any Funded Intellectual Property which appears to the Host Institution to have potential to be translated to deliver patient benefit or which can otherwise be exploited commercially, the Host Institution shall notify ME Research UK in writing giving full details of such Funded Intellectual Property.

8.1.8

ME Research UK must be notified in good time (and in any event at least thirty (30) days) before either presentation or publication of any Results, whether patentable or not, which appear to

be suitable for commercial exploitation or that are otherwise worthy of protection. At ME Research UK's request, the dissemination of Results will be delayed to enable the protection of Funded Intellectual Property.

8.1.9

The Host Institution shall plan and prepare the necessary steps to be taken to protect Funded Intellectual Property as is reasonable to do so with regard to commercial considerations, however it shall not make (or permit others to make) any application for registered protection (including a patent) in connection with Funded Intellectual Property without the prior written consent of ME Research UK.

8.1.10

If the Host Institution decides to withdraw or abandon patent or similar protection in respect of Funded Intellectual Property, ME Research UK shall be entitled to take an assignment of the property concerned and the Host Institution shall give ME Research UK no less than sixty (60) days' notice to allow it to do so effectively.

8.1.11

The Host Institution may not exploit, or grant any third parties the right to exploit, Funded Intellectual Property without the prior written consent of ME Research UK. Where ME Research UK consents to such exploitation, it may impose such conditions in respect thereof as it sees fit.

8.1.12

ME Research UK retains the right to call for an assignment to ME Research UK of all Funded Intellectual Property. Such right is likely only to be exercised in exceptional circumstances. After such an assignment has been completed ME Research UK and the Host Institution shall negotiate in good faith to agree the terms of a revenue share agreement in respect of net income received by ME Research UK arising from the commercial exploitation of such Funded Intellectual Property.

8.1.13

If, notwithstanding the prohibition in Section 8.1.11, Funded Intellectual Property is exploited commercially without ME Research UK's prior written consent, the Host Institution shall:

i. pay or transfer (as appropriate) to ME Research UK sixty *per centum* (60%) of all gross income and any other sums (whether in cash or otherwise) received by the Host Institution (or by any third party authorised by the Host Institution) from the exploitation of the Funded Intellectual Property, without any deduction of any costs, taxes or any other sums. However, if:

(i) a third party contributes towards the directly incurred costs of the research which led to the creation of the Funded Intellectual Property; or

(ii) ME Research UK provides additional funding (over and above the directly incurred costs), then the foregoing revenue share shall be adjusted as ME Research UK deems appropriate;

ii. account to ME Research UK for its revenue share on a quarterly basis, in pounds sterling;

- iii. be solely responsible for rewarding the inventors of Funded Intellectual Property out of its share of gross income;
- iv. provide ME Research UK with a quarterly statement summarising all income received and costs incurred; and
- v. ensure that proper books and records are kept (recording all exploitation activities and all income received/costs incurred) and allow ME Research UK access to such books and records as ME Research UK may reasonably request from time to time.

8.1.14

ME Research UK encourages the transfer of samples of Funded Materials to academic and other not-for-profit third parties solely for the purposes of non-commercial research, under the terms of a material transfer agreement substantially in a form approved by ME Research UK. The Host Institution may not transfer Funded Materials to any commercial entity without ME Research UK's prior written consent.

8.1.15

The Host Institution shall retain copies of all agreements (including collaboration agreements, material transfer agreements and confidential disclosure agreements) proposed and/or completed relating to Funded Intellectual Property. The Host Institution shall provide ME Research UK with copies of such agreements as ME Research UK may request from time to time. For further details contact: meruk@pkavs.org.uk

8.2 Clinical Trials

8.2.1

ME Research UK expects that the host institution shall own all Clinical Trial Results.

8.2.2

Where a Clinical Trial is supported in any way by a commercial entity, the Host Institution shall be responsible for negotiating any agreements with such commercial entity, provided that where the Host Institution intends to grant such entity any rights in respect of Clinical Trial Results:

- i. the Host Institution notifies ME Research UK of such commercial interest as soon as practicable; and
- ii. the Host Institution leads the negotiations with the commercial entity, but regularly consults with ME Research UK (or, at ME RESEARCH UK's request, with ME Research UK's nominees or assignees whomsoever) and incorporates all amendments relating to such grant of rights that it (or ME Research UK) may suggest.

Such agreement should normally be put in place after the relevant Clinical Trial has been completed.

8.2.3

The Host Institution will promptly notify ME Research UK following receipt by the Host Institution of any monetary consideration from a commercial entity in respect of rights granted to Clinical Trial Results. Following such notification, the Host Institution will negotiate and enter into an appropriate revenue sharing agreement with ME Research UK (or, at ME Research UK's request a nominee or assignee thereof) under which it will share with ME Research UK (or with ME Research UK's nominees or assignees whomsoever) a fair proportion of such monetary consideration (which shall at least reimburse ME Research UK for the corresponding amount of funding it has provided in support of the relevant Clinical Trial, whether in respect of the set-up/management of the trial or any other costs).

9 PUBLICATION, PUBLICITY AND REPORTING

9.1 Publication

9.1.1

The Grant Holder must comply with ME Research UK's policy on data sharing and preservation by ensuring that they have a data management and sharing plan as part of their application. Please refer to our website for further details.

9.1.2

ME Research UK requires Researchers to promulgate the results of the research that it funds in the usual manner, for example by publication and by presenting at meetings. ME Research UK has the right to require publication to be delayed to meet reasonable requirements for the protection of Intellectual Property Rights, fundraising and other matters, but this will not be applied unnecessarily.

9.1.3

Before publication, the Host Institution must ensure the Research undergoes the Host Institution's standard procedures for ensuring the validity of the results and the suitability of the research for general publication. ME Research UK takes no responsibility for the validity of the Results or for any statements made by the authors in the publication.

9.1.4

Under UK charity law, ME Research UK has an obligation to make available information about the work that it funds and will respond to changes in the way that information of this type is exchanged. It is a condition of funding that ME Research UK Grant Holders deposit an electronic copy of peer-reviewed, published papers arising from their ME Research UK funded work in the UK

9.1.5

Subject to any agreement between the Host Institution and ME Research UK, Grant Holders are required to consult ME Research UK in accordance with Section 9.1.8;

9.1.6

Grant Holders must provide ME Research UK with details of all publications arising from the research, whether wholly or partly funded. Details should be provided at the time of submission for publication to ensure that ME Research UK is kept fully informed of all Results entering the public domain and has sufficient notice to arrange any publicity.

9.1.7

Studies involving human subjects represent a special case, especially if the publication, either in print or electronic format, of the results enables individuals (the subjects or others) to gain knowledge about their personal condition which they otherwise would not have had. In any clinical study where this is possible the matter must be addressed in the protocol and discussed with a Research Ethics Committee.

9.1.8

Investigators must consider whether a mechanism is needed for human subjects to be made aware of the results and the implications for them personally before publication (communication with their GP or the consultant entering them into the trial, with a clear indication of their responsibility for communicating to the patient, would be deemed to be sufficient). If such a mechanism is put in place, there must also be procedures for dealing with any consequences arising from its use.

9.2 UK PubMed Central (UKPMC).

9.2.1

ME Research UK aims to fund world-class research to identify the causes, consequences and treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) or any other related illnesses and find out how best to prevent, diagnose and treat the disease.

ME Research UK believes that there is a need to provide open and unrestricted access to the outputs of published research. In this way we can ensure that the work we fund can reach the widest possible audience

9.2.2

ME Research UK expects authors of research papers based on ME Research UK funded research to maximise the opportunities to make their results freely available.

It is a condition of funding that ME Research UK funded researchers deposit in the UKPMC database an electronic copy of the author's final version of papers accepted for publication. This should happen as soon as possible and no later than 6 months after publication. This requirement applies to research supported in whole, or in part, by ME Research UK

This obligation may be achieved through one of two routes.

(i) a manuscript may be submitted to a journal that offers an Open Access (OA) option. The journal will then deposit a copy of the final article in the UKPMC database. A number of new publishers, such as BioMed Central and Public Library of Science, as well as traditional publishing houses, such as Elsevier, OUP and Blackwell, support this option. Payment of any open access fees may be met from underspend on existing grants, or

(ii) Researchers may, alternatively, submit manuscripts to a publisher that does not offer an OA option but does permit a copy of the research article to be deposited, and made publicly available, in UKPMC. Publishers that offer this option include American Medical Association, Company of Biologists and Nature Publishing Group.

However, ME Research UK does not wish to prevent researchers from submitting research publications to the most appropriate journal, some of which may not be compliant with this policy. As a result ME Research UK funded researchers may publish in **exceptional circumstances** in a journal that would not allow the article to be deposited in UKPMC within 6 months.

9.2.3

Researchers must seek prior approval from ME Research UK if such publication is contemplated and justify, to the satisfaction of ME Research UK, why publication in a journal which that would not allow the article to be deposited in UKPMC is appropriate.

9.3 Acknowledgement of Support

9.3.1

In any oral or written report or poster presentation of Results or otherwise relating to the Research, the author must acknowledge the support of ME Research UK. All references to ME Research UK funded work placed on websites, electronic bulletin boards and similar must state clearly that the work is funded by ME Research UK and, where practical, should include a link to ME Research UK's website, <http://www.mereseach.org.uk/>

9.3.2

It is essential that investigators acknowledge that their research has been supported wholly or in part by ME Research UK using a format similar to, "This work was supported by ME Research UK (SCIO charity number SC036942)".

9.4 Publicity

9.4.1

In order to safeguard future voluntary income and maintain our reputation for world class science, it is essential that ME Research UK is widely known and respected among the scientific community, the media and among fundraisers and the general public. All opportunities to promote ME Research UK must therefore be fully exploited and Grant Holder and the Host Institution are obliged to co-operate with ME Research UK over any publicity or fundraising activity arising from ME Research UK funded research. Where ME Research UK is the main funder of the research, ME Research UK reserves the right to lead on publicity. Grant Holders and the Host Institution are required to contact ME Research UK prior to any publicity releases about ME Research UK funded research.

9.4.2

When speaking publicly about their research and particularly when speaking to representatives of the media, Researchers should ensure that they are recognised as a ME Research UK funded scientist. However, Researchers should not speak to the media as a 'ME Research UK funded scientist' without prior consultation with the press office.

9.4.3

There is a subtle but important difference between speaking as an 'ME Research UK funded scientist' and acting as a spokesperson for the charity, which Researchers are not authorised to do. Representatives of the media may not always be aware of this difference and Researchers who speak to the media must ensure that their personal views are not misrepresented as being attributable to ME Research UK.

9.4.4

ME Research UK reserves the right to use data or other material from research that it funds as part of its fundraising or publicity activities.

9.4.5

Grant Holders are required to submit publishable information about their proposed research and limited publishable contact information at the time of application. If the application is funded, these details will be published on ME Research UK's website. A publishable abstract must be submitted for all successful awards and failure to submit will delay the activation of the award.

9.5 Open Access to Data

It is acknowledged that to best foster scientific progress, the underlying data arising from ME Research UK's funded projects should be made freely available for researchers to use, wherever this is legal and ethical. Data availability allows replication, reanalysis, new analysis, interpretation, or inclusion into meta-analyses, and facilitates reproducibility of research. Grant holders are encouraged to adopt a position of data openness, with the presumption in favour of data release consistent with law, regulation and recognised good practice.

10 FUNDRAISING & VOLUNTEERING

10.1

World class research relies on world class fundraising and much of our fundraising is strengthened by the presence and collaboration of our scientists. ME Research UK expects Grant Holders and Research Personnel to contribute as much as possible. Contributions could be by hosting lab tours, speaking at fundraising events, volunteering at national events or actively participating in events or otherwise promoting or explaining the work of the charity and the research undertaken as a result of the financial support of ME Research UK.

10.1.1

Fundraisers may use your work as examples for our supporters - to demonstrate the impact of funds raised. That may mean we will use our researchers' images and ask for help with quotes, copy etc. Further to this, we may use specific projects from our research portfolio to generate donations and then ring fence those gifts to those projects. Donations generated using this method are not extra funds on top of the agreed budget allocated to the Grant Holder or Research Personnel concerned.

10.1.2

The public activity described in Section 10.4.1 can sometimes generate publicity. Where possible ME Research UK will contact you to make you aware of this beforehand, however, this is something that cannot always be foreseen.

11 HUMAN BIOLOGICAL SAMPLES

11.1 Tissue Samples

ME Research UK recognises and supports the need for high quality human tissue collections for research. ME Research UK requires all ME Research UK funded research and tissue sample collections to be carried out in compliance with the requirements of the Human Tissue Act 2004, which extends only to England, Wales and Northern Ireland and the Human Tissue (Scotland) Act 2006.

11.1.1

Grant Holders must declare if any of ME Research UK's monies, resources or manpower are used in total or in part to collect, process, retain or distribute human tissue samples. Grant Holders must confirm in a signed statement that the processes that they follow comply with the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 respectively, and applicable research governance arrangements.

11.1.2

To ensure that tissues or sample collections are built and maintained in a cost-effective manner and used efficiently and effectively, Grant Holders who hold tissue or sample collections are

required to record information detailing the purpose and scope of the sample collection or tissue holdings together with any additional information ME Research UK deems necessary.

11.1.3

In supporting the principle of making best use of human samples for the benefit of all, recipients of ME Research UK funding or those who draw support from ME Research UK funded tissue sample collections may be required as a condition of funding to contribute data generated from the use of that human tissue in a form that can be utilised as part of any national bioinformatics grid.

11.1.4

ME Research UK requires that principles governing access to the samples collected are established. This will enable access to the collection by other potential researchers in the future.

12 STUDENTSHIPS

12.1 Studentships Award

12.1.1

Studentships funded by ME Research UK may provide the following:

- i. a stipend set by ME Research UK
- ii. running expenses
- iii. standard university consolidated fees
- iv. college fees for Oxford and Cambridge.

But will not exceed the rate set by Research Councils UK

12.1.2

ME Research UK will only pay fees at the UK/ EU level. However, there are no restrictions on the nationality of the ME Research UK funded PhD student.

12.1.3

ME Research UK will not pay expenses for interviewing candidates.

12.1.4

The Host Institution is expected to provide the student the stipend at the level set by ME RESEARCH UK, for four years. ME Research UK will not pay more than the stipend specified.

12.1.5

The Grant Holder must notify ME Research UK of the student's start date within thirty (30) days of the start date.

12.1.6

ME Research UK does not encourage registration for PhD or MPhil by research assistants or technicians unless they transfer to a studentship. Running Expenses on awards cannot be used to allow Research Personnel to register for PhD, MD or MPhil awards.

12.1.7

If the student has to take time out of their studies due to illness or maternity leave the guidelines of your Host Institution must be followed. The leave and requests for extensions should then be discussed with ME Research UK.

12.1.8

Depending on local arrangements and agreement from the supervisor, students may spend up to 10 per cent of their time undertaking teaching duties. However, if they are paid for this activity students may become liable for tax and this should be carefully checked before undertaking such work.

12.1.9

ME Research UK requires the title, a copy of the abstract page, and confirmation of the outcome of the viva voce examination. Students and supervisors must also complete the final year report.

12.1.10

If a student fails to complete their PhD, ME Research UK must be informed of the reason.

13 LIMITATION OF LIABILITY

13.1

ME Research UK accepts no responsibility for costs or liabilities incurred in connection with the research or other work funded by a ME Research UK award other than those costs specifically set out in the GAL and in these Terms and Conditions.

13.1.1

ME Research UK takes no responsibility for expenditure incurred before the award is activated or after the Grant has been closed.

13.1.2

ME Research UK cannot be responsible for liabilities arising out of the acts or omissions of the Host Institution, the Grant Holder, or others involved in the Research or other work funded by a ME Research UK award and the Host Institution hereby indemnifies ME Research UK against any costs, claims or liabilities suffered or incurred by ME Research UK as a result of any action, claim or complaint brought by a third party against ME Research UK arising out of or in connection with the research or other work.

13.1.3

ME Research UK shall not be held responsible for any loss or liabilities if it transpires that an award is ineligible for government support through one of the Higher Education Funding Councils or other schemes.

13.1.4

ME Research UK is not liable for loss or injury caused or deemed to be caused by the use or misuse of any equipment funded under the Grant.

13.1.5

ME Research UK requires the Host Institution to provide a no-fault compensation scheme for participants in a ME Research UK funded clinical trial as per the relevant local ethics committee approval. ME Research UK does not provide indemnity cover for or accept any liability for harm to participants in ME Research UK funded trials where ME Research UK is not the Trial sponsor.

14 VARIATION & TERMINATION

14.1

All grants awarded by ME Research UK are subject to the terms and conditions that apply at the time the grant is awarded and any subsequent amendments. ME Research UK reserves the right to amend these Grant Conditions, any terms and conditions of the GAL and the Funding Policies from time to time. ME Research UK may publish any change to the Grant Conditions or the Funding Policies on its website.

14.2

In the event of a conflict between the provisions of these Grant Conditions as amended from time to time and of the Grant Award Letter, the provisions of the Grant Award Letter will take precedence.

14.3

ME Research UK reserves the right to withhold or suspend the Grant with immediate effect.

14.4

ME Research UK reserves the right to terminate the Grant with sixty (60) days' notice.

15 GOVERNING LAW

These Grant Conditions shall be governed by and construed in accordance with Scots Law. The Host Institution and the Grant Holder(s) irrevocably submit to the exclusive jurisdiction of the Scottish Courts to settle all matters in connection with the Grant Conditions.

16 RELATED DOCUMENTS

Clinical Trials Policy on Medicines for Human Use Policy on clinical trials in response to the implementation of the Medicines for Human use (clinical trials) Regulations 2004.

Open Access and UK PubMed Central

Policy on Open Access Publication and submission of publications to UK PubMed Central.

ME Research UK Conflict of Interest and other Policy Documentation

17 UNDERTAKINGS (AWARD) FORM: Example

UNDERTAKINGS (AWARD) FORM

Principal Investigator:

Project Title:

Undertakings required when accepting an award

The Principal Investigator, Head(s) of Department and appropriate Administrative Authority are required to sign this form when accepting an award. The form should be returned to the Administrator at ME Research UK within four weeks if the offer is accepted.

Principal Investigator

I accept the award from ME Research UK and agree to abide by the standard terms and conditions (including Conflict of Interest Policies) being the Grant Funding Conditions (2018) and any supplementary terms and conditions agreed in the Grant Award Letter.

I acknowledge receipt of, have read, and agree to be bound by ME Research UK's Grant Funding Conditions (2018) and any supplementary terms and conditions agreed in the Grant Award Letter.

Name..... Signature..... Date.....

Head(s) of Department

I confirm that I agree to this research being carried out in my Department and that the facilities defined in the application will be made available.

Name..... Signature..... Date.....

Name..... Signature..... Date.....

Administrative Authority (e.g. Registrar, Vice-Chancellor's Office, Secretary of Institute)

I accept this award on behalf of:

Institution.....

and confirm that this Institution will administer the grant. I have read and the Institution accepts the standard terms and conditions being the Grant Funding Conditions (2018) and any supplementary terms and conditions agreed in the Grant Award Letter.

Name..... Signature..... Date.....

Position.....

Signed on behalf of ME Research UK

Name..... Signature..... Date.....

ME Research UK

Scottish Charitable Incorporated Organisation No. SC036942

The Gateway, North Methven Street

Perth, PH1 5PP, UK

www.mereseach.org.uk

FINAL REPORT TO ME RESEARCH UK

A Final Report must be submitted no later than three months after the grant ends. The charity trustees require:

1. A brief summary report for the lay reader, in not more than 300 words, describing the original objective(s) of the scheme, the activities undertaken, and the achievement of the scheme. This section is important for the benefit of non-scientific persons, the public and donors who wish to understand the outcomes and benefits of the research. It is also necessary to allow ME Research UK to promote the award and outcomes to a wider audience.
2. A brief summary defining the relevance of the research to ME Research UK's charitable objectives. ME Research UK reserves the right to request a satisfactory replacement of the above.
3. A fuller report (not more than 3,000 words), accompanied by a final statement of expenditure under the various budget heads, explaining the organisation, history, and essential details of the grant and its achievements. You may include drafts of potential publications with this final report.

The full report should be organised under the following headings:

- (a) **The grant:** a brief 'history': start and completion dates, size of budget, names of people involved and visitors (with duration of visits for each participant), site(s) of research activity.
- (b) **Objectives:** a brief statement.
- (c) **Research activity:** sources and/or methods used, problems encountered, type of work involved, and results.
- (d) **Conclusions and achievements:** extent to which the exchanges were successful, original contribution of research to theoretical and/or practical knowledge, significance for general research in this field, personal evaluation of outcome, including unsuccessful as well as successful elements.
- (e) **Publications and dissemination:** list actual and prospective publications and other means of disseminating results. Copies of published material, acknowledging ME Research UK support, should be sent to the charity. Unpublished reports should also be sent, together with an explanation of why private circulation was preferred. The trustees recognise that publication may take a considerable time, but wish to receive in due course copies of all publications resulting from the work.
- (f) **Future plans:** for exchanges and research in the field.

PUBLICITY AND PUBLICATION OF RESEARCH FINDINGS

Researchers are reminded that in the terms of ME Research UK's Grant Funding Conditions (2018), or any replacement thereof, ME Research UK requires (among other obligations) grant holders to:

1. Provide ME Research UK with details of all publications arising from the research, whether wholly or partly funded. Details should be provided at the time of submission for publication to ensure that ME Research UK is kept fully informed of all results entering the public domain and has sufficient notice to arrange any publicity.
2. Promulgate the results of the research that it funds in the usual manner, for example by publication and by presenting at meetings.
3. Deposit an electronic copy of peer-reviewed, published papers arising from their ME Research UK-funded work in the UK with ME Research UK.
4. Deposit in the UKPMC database an electronic copy of the author's final version of papers accepted for publication. This should happen as soon as possible and no later than six months after publication.
5. Contact ME Research UK prior to any publicity releases about ME Research UK-funded research.

In order to safeguard future voluntary income and maintain our reputation for world class science, it is essential that ME Research UK is widely known and respected among the scientific community, the media and among fundraisers and the general public. All opportunities to promote ME Research UK must therefore be fully exploited and the grant holder and host institution are obliged to co-operate with ME Research UK over any publicity or fundraising activity arising from ME Research UK-funded research.

ME Research UK expects grant holders and research personnel to contribute as much as possible. Contribution could be by hosting lab tours, speaking at fundraising events, volunteering at national events or actively participating in events or otherwise promoting or explaining the work of the charity and the research undertaken as a result of the financial support of ME Research UK.