

HEALTH INNOVATION CHALLENGE FUND

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These Grant Conditions, which form part of the **Contract Documents**, set out the terms and conditions on which the Grant is made by the Grantors to the Organisation. These Grant Conditions are subject to a **Funding Agreement** between the Grantors and the Organisation.

The Wellcome Trust policies and positions for grants are available on the Wellcome Trust's website www.wellcome.ac.uk/about-us/policy/policy-and-position-statements/index.html and hard copies are available on request by e-mail to grantenquiries@wellcome.ac.uk. The Department of Health policies are available on the Department of Health website www.dh.gov.uk.

The Organisation must ensure that the Grantholders and others supported by the Grant are made aware of and comply with all Contract Documents.

The Grantors may exercise their rights pursuant to these Grant Conditions jointly or individually.

1. ADMINISTRATION

- 1.1 Initial payments will not be made from the Grant until twenty (20) Business Days following the date of the last signature to the Funding Agreement. Any further payments will be made 20 Business Days after the Grantors' written confirmation to the Organisation that a project milestone has been met, pursuant to the Organisation submitting a detailed Milestone Report and Drawdown Notice according to the Funding Agreement.
- 1.2 The Organisation must ensure that sufficient resources are provided to support the activities described in the Funding Agreement.
- 1.3 The Department of Health and the Wellcome Trust both support research activities but their funding mechanisms differ. Consequently the final funding provided to a successful applicant will reflect the combination of the two approaches. The Department of Health will fund at up to 100% of FEC. The Wellcome Trust will fund the directly incurred costs and certain other allowable costs, as detailed on the Wellcome Trust's website (<http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX026852.htm>). Successful applicants will receive an Award Letter in which the amounts contributed by each of the Grantors will be set out together with the allowable costs awarded.
- 1.4 The Grantors must be consulted in the event of any material change in the proposed research, including failure to gain access to facilities or services or to gain ethical committee approval. If appropriate, revised proposals may be required. In such an event the Grantors reserve the right to revise or terminate the Grant.
- 1.5 The duration of the Grant Period may be extended by periods up to a total maximum of six (6) months, with the prior written consent of the Grantors. Extensions may cover breaks or delays in the appointment of staff, periods of maternity leave, paternity leave, adoption leave, parental leave or paid sick leave exceeding 3 months (or possibly shorter periods of sick leave if the member of staff is disabled as defined in the Disability Discrimination Act 1995) or other exceptional cases with the prior written consent of the Grantors.
- 1.6 The Grantors shall have the right to seek reimbursement in the event of an overpayment in relation to any Grantors grant made to the Organisation, including by setting such overpayment off against payments due under other Grantors grants to the Organisation or any other payments which the Grantors are due to make to the Organisation. The Grantors shall also have the right to suspend payments to the Organisation in the event of non-delivery of a Spend Report or an End of Grant Spend Report or where the Organisation has failed to respond to any queries raised by the Grantors in relation to a Spend Report or an End of Grant Spend Report, to the reasonable satisfaction of the Grantors.
- 1.7 The Grantors reserve the right to amend the payment profile at their discretion. The Organisation will be advised at least thirty (30) days in advance of any such change.

2. RESEARCH PRACTICE AND ETHICS

- 2.1 The Organisation shall ensure that the research is conducted using good laboratory notebook practice. There must be effective and verifiable systems in place for managing research quality, progress and the safety and wellbeing of patients and other research participants. The Organisation shall manage and monitor statutory requirements for medical and health research, including legislation on clinical trials and use of human organs, tissues and data.
- 2.2 The Organisation shall ensure that before the research funded by the Grant commences and during the Grant Period that there is clarity of role and responsibility among the research team and any collaborators. The Grantors expect the research to be conducted in accordance with the highest standards of scientific integrity and research methodology. Where any element of the research funded by the Grant is to be conducted outside the UK,

such legal and regulatory requirements, and such licences and approvals should include those applicable in the additional countries involved.

- 2.3 The Organisation will ensure that research in any way connected with the Grant is conducted in accordance with the Department of Health Guidance "Research Governance Framework for Health and Social Care" and, if relevant, in accordance with the Department of Health guidance "Governance Arrangements for NHS Research Ethics Committees" or such other guidelines as may be issued from time to time by the Department of Health and copies of which are made available to the Organisation.
- 2.4 The Organisation shall comply with all relevant legislation including but not limited to:
- a) the Medicines for Human Use (Clinical Trials) Regulations (SI2004/1031);
 - b) the Human Tissue Act 2004;
 - c) the Animals (Scientific Procedures) Act 1986.
 - d) the Data Protection Act 1998.
- 2.5 The Organisation will submit for review by a Research Ethics Committee recognised by the Grantors any project involving:
- a) NHS patients and users including those treated under agreement with private sector providers;
 - b) individuals identified as potential research participants because of their status as relatives or carers of NHS patients;
 - c) NHS staff - recruited as research participants by virtue of their professional role;
 - d) access to data, organs or other bodily material (including foetal material) of past and present individual and identifiable NHS patients;
 - e) IVF involving NHS patients;
 - f) the recently dead in NHS premises;
 - g) the use of, or potential access to, NHS premises or facilities;
 - h) animals

with a view to obtaining the approval of the Research Ethics Committee to the project and will inform the Grantors when such approvals have been given (whether unconditionally or subject to conditions) or withheld.

- 2.6 Where possible, the Organisation should adopt procedures and techniques that avoid the use of animals. Where that is not possible, any research involving animals undertaken by the Organisation, collaborators or service providers in the UK or internationally must comply with (i) the Wellcome Trust's policy on the use of animals in research and the principles set out in the document "Responsibility in the use of animals in bioscience research: Expectations of the major research council and charitable funding bodies" (<http://www.welcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD040129.htm>), and (ii) Home Office advice on ethical review practice in relation to the Animals (Scientific Procedures) Act 1986. If procedures regulated under the Animals (Scientific Procedures) Act 1986 will be used, the research must comply with the Act, be approved by the local ethical review process and be conducted with due consideration for the 3Rs (replacement, reduction and refinement of the use of animals in research). The Organisation must ensure that research involving the use of animals complies at all times with the relevant laws and regulation in the host country. Any element

of research funded by the Grant that is conducted outside the UK must, as a minimum standard, be conducted in accordance with the principles of UK legislation (including the Animals (Scientific Procedures) Act 1986).

2.7 The Organisation must ensure that it has in place formal written procedures for managing the process for obtaining any necessary or appropriate ethical approval for the research funded by the Grant, and must accept full responsibility for ensuring that any such ethical approval is in place at all relevant times during the Grant and before any work requiring approval commences.

2.8 The Organisation must have in place formal written procedures for the handling of allegations of research misconduct, such procedures to meet at least the minimum criteria set out in the Trust's statement on the handling of allegations of research misconduct.

3. **AUDIT**

3.1 Where applicable, the Organisation must ensure that any part of the of the research project not eligible for funding by the Grantors has been secured from other sources before the commencement of the project. For example, NHS Support or Treatment Costs and, for HEIs, any part of the Directly Allocated costs or Indirect costs not supported by the Grantors.

3.2 The value of the Grant may not be increased and is provided solely for use in the Project. Under no circumstances may Directly Incurred Costs funds or Exceptions funds be applied to meet costs on any other activity without the prior written permission of the Grantors.

3.3 The control of expenditure to be funded under the Grant must be governed by the normal standards and procedures of the Organisation and must be covered by any formal audit arrangements that exist in the Organisation.

3.4 During the Grant Period and for six years thereafter, the Grantors (and/or the National Audit Office or Audit Commission) shall have the right to request from the Organisation, at any time, any financial information or technical information or results of the research in respect of the Grant or the activities it funds and/or to ask for confirmation from the external auditors of the Organisation that the external auditors have signed their opinion on the annual accounts of the Organisation without qualification; and the management letter from the auditors raises no matters that did or could significantly affect the administration of grants awarded by the Grantors. If the auditors have raised any such matters in their management letter, the Grantors (and/or the National Audit Office or Audit Commission) may require the Organisation to provide them with relevant extracts from the letter.

3.5 During the Grant Period and for six years thereafter, the Organisation must provide access to accounting and other records relating to the Grant and the activities funded by it for auditors and other personnel from or appointed by the Grantors (or the National Audit Office or Audit Commission) at any time (at the auditing Grantor's expense), if requested. Such access must include the right to inspect any equipment or facilities acquired or funded under the Grant, laboratory notebooks or other records of research carried out using the Grant and any outcomes of such research. For the avoidance of doubt, audit may include audit of technical and scientific work and patient benefit as well as financial audit. Where elements of expenditure under the Grant have been subcontracted, the Organisation should ensure that the right of access extends to the accounts, records, procurement procedures (and records of procurements), equipment and facilities of any such subcontractor.

3.6 During the Grant Period and for six years thereafter, the Grantors (and/or the National Audit Office or Audit Commission) shall have the right, at their discretion and expense, to audit (directly or via third parties engaged by it) the Grant, income and expenditure in relation to the activities funded by the Grant and/or the systems used by the Organisation to administer the Grant at any time and compliance with the Grant Conditions.

3.7 The Organisation should maintain a separate accounting cost code specific to the Grant, and all costs and income properly relating to the Grant should be accounted for through that

cost code. The Organisation should ensure that appropriate records are kept to support the entries made on the cost code.

4. **EQUIPMENT**

4.1 The Organisation 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 it using these procedures. Procurement of equipment, consumables and services must comply with all relevant EU procurement law.

4.2 The Organisation must ensure that equipment purchased with Grant funds is appropriately insured and maintained during the period of the Grant.

4.3 Equipment funded by the Grant is awarded to the Organisation specifically for the research for which the Grant is awarded. Written prior permission from the Grantors must be obtained to use the equipment for any other purpose (including charging, hiring, lending or disposing of it). The Grantors must be informed if, during the Grant Period, the need for the equipment diminishes substantially or it is proposed to use it for other research purposes. In such event, the Grantors reserve the right to determine the disposal of such equipment and to claim the proceeds from any sale.

5. **EMPLOYMENT**

5.1 The Grantors do not act as an employer with respect to the Grant, and therefore in all cases where support is provided on the Grant for the employment of staff, the Organisation undertakes to issue a contract of employment to such staff that is in compliance with relevant laws and regulations. The Grantors accept no liability and disclaim all and any liability for any employees the Organisation uses to carry out the work on the Grant funded research, including without limitation any liability in respect of unfair dismissal, discrimination, breach of employment contracts or employment law or any TUPE liabilities.

5.2 The Organisation shall have full responsibility for all staff funded from the Grant and, in consequence, fulfil all duties and obligations owed as an employer to such staff.

5.3 The Organisation shall ensure that any individuals employed by or having a contract for services with the Organisation who are involved in any way with activities funded by the Grant comply with the rules and regulations of the NIHR faculty as set out in the Department of Health's "NIHR Faculty Regulations".

6. **UNLAWFUL DISCRIMINATION**

6.1 The Organisation shall ensure that it complies with all current employment legislation and in particular, does not unlawfully discriminate within the meaning of the Race Relations Act 1976 (as amended), the Sex Discrimination Act 1975 (as amended) and 1986, the Disability Discrimination Act 1995 (as amended) and 2005, the Equality Act 2006, the Employment Equality (Religion or Belief) Regulations 2003 [SI 2003 No 1660] (as amended), The Employment Equality (Sexual Orientation) Regulations 2003 [SI 2003 No 1661] (as amended), the Employment Equality (Sex Discrimination) Regulations 2005, the Employment Equality (Age) Regulations 2006, or any other relevant legislation relating to discrimination in the employment of employees (collectively, the "Employment Legislation").

6.2 The Organisation shall notify the Grantors immediately of any investigation of or proceedings against the Organisation under the Employment Legislation and shall cooperate fully and promptly with any requests of the person or body conducting such investigation or proceedings, including allowing access to any documents or data required, attending any meetings and providing any information requested.

6.3 The Organisation shall indemnify the Grantors against all costs, claims, charges, demands, liabilities, damages, losses and expenses arising out of or in connection with any investigation conducted or any proceedings brought under the Employment Legislation due

directly or indirectly to any act or omission by the Organisation, its agents, employees or sub-contractors.

7. PUBLICATION, PUBLICITY AND REPORTING

- 7.1 The findings from research funded by the Grant should be published in an appropriate form, usually as papers in a refereed, peer-reviewed journal.
- 7.2 The publication or release of such findings may be reasonably delayed to enable protection of any intellectual property. The identification, protection, management and exploitation of intellectual property is subject to Clause 10 on "Intellectual property and commercial activities".
- 7.3 All research papers that have been accepted for publication in a peer-reviewed journal, and are supported in whole or in part by the Grant, must be made available from UK PubMed Central as soon as possible, and in any event within six months of publication, in line with the Wellcome Trust's Open Access policy (available at <http://www.wellcome.ac.uk/node3302.html>).
- 7.4 Grantors may at any time publish any report, executive summary, paper, abstract or other document provided by the Organisation for any non-commercial purpose and in conjunction with the Grantor's statement on Open Access to research "Statement on DH/NIHR-funded research and UK PubMed Central". Such purposes may include but are not limited to any entry in a register of research findings or an individual issue of or a review article in a monograph series prepared on the Grantor's behalf. The timing of any such publication will be subject to consultation with the Organisation and will take account of publication timetables in other peer-reviewed journals and the need to make research findings publicly available as soon as practicable.
- 7.5 To assist the Grantors in tracking the outputs of research to which they have contributed funding either wholly or in part, the Grantors' contributions must be acknowledged in all publications and other forms of media communication including media appearances, press releases and conferences according to the Wellcome Trust's Guidance for Research Publication Acknowledgement Practice (available from http://www.wellcome.ac.uk/doc_wtx038642.html) and the Department of Health's statement on Open Access in research (available from <http://www.nihr.ac.uk>).
- 7.6 To meet the Grantors' obligations for public accountability and the dissemination of information, details of Grants may also be made available on the web sites of each of the Grantors and other publicly available databases and in reports and documents.
- 7.7 The form and content of the End of Grant Research Report and the End of Grant Spend Report shall be as directed by the grantors at www.wellcome.ac.uk/hicf.

8. FREEDOM OF INFORMATION

8.1 Attention is drawn to the Freedom of Information Act 2000 ("FOIA") and the Environmental Information Regulations ("EIRs"). The Department of Health ("DOH") has a publication scheme which sets out the type of information publicly available on its website or published as documents. In addition, the DOH has an obligation to respond to specific requests and may be required to disclose information about or provided by the Organisation. In some cases the DOH may consult the Organisation before deciding whether to disclose information requested under the FOIA, but it is not obliged to do so. If an Organisation considers that any information it provides to the DOH would be subject to an exemption under FOIA or the EIRs it should clearly identify such information and explain why it considers the information exempt. The DOH will consider such explanation. For the avoidance of doubt, notwithstanding the previous sentence, whether or not information will be disclosed shall be at the DOH's sole discretion.

8.2 Where the DOH considers that an Organisation is holding information that it requires in order to comply with its obligations under FOIA or the EIRs, the Organisation undertakes to (and shall procure that its collaborators and sub-contractors shall) provide access to such information as soon as reasonably practicable, at its own expense and at no charge to the DOH, on the request of the DOH and in any case within five working days.

9. DATA PROTECTION, PERSONAL DATA and MEDICAL RECORDS

9.1 The Organisation shall ensure that the collection, handling and use of personal data (as defined in the Data Protection Act 1998 ("DPA") shall be treated as confidential at all times, and stored securely (including in any electronic format).

9.2 Any and all medical information used by the Organisation in carrying out a Grant-funded research shall be used in accordance with the following guidance (as updated from time to time):

- (a) the Medical Research Council's "Personal Information in Medical Research", January 2003 available at <http://www.mrc.ac.uk>; and
- (b) "The NHS Confidentiality Code of Practice", guidelines on the use and protection of patient information, November 2003 available at <http://www.dh.gov.uk>

9.3 No information which could lead to the identification of an individual shall be included in any publication without the prior agreement in writing of the individual concerned.

9.4 The Grantors shall not be entitled to inspect, take or be supplied with copies of any specific basic factual (or "raw") data obtained in connection with the Grant-funded research other than in an anonymised form. The Organisation shall ensure that all basic factual data is anonymised as and when it is obtained and that the key to personal identities of all persons to whom the data relates is kept in a separate and secure place.

9.5 The Organisation shall fully indemnify and hold harmless the Grantors, their directors, officers, employees and agents against all liabilities, losses, costs, charges and expenses incurred as a result of any claims, demands, actions and proceedings made or brought against the Grantors by any person in respect of any loss or distress to that person by the loss, unauthorised disclosure of personal data or medical records by the Organisation, or any collaborator, sub-contractor, servant or agent of the Organisation or any person within the control of the Organisation.

9.6 The Organisation shall at its own expense conduct any litigation arising from any such claims, demands, actions or proceedings and all the negotiations for the settlement of the

same and the Grantors hereby agree to grant the Organisation exclusive control of any such litigation or the negotiations for the settlement of the same.

10. INTELLECTUAL PROPERTY AND COMMERCIAL ACTIVITIES

- 10.1 The Organisation shall notify the Grantors of any Project Intellectual Property which is capable of exploitation (whether patentable or not) in a timely manner.
- 10.2 The Organisation shall develop, implement and maintain procedures for the management of Project Intellectual Property and shall use reasonable endeavours to ensure that:
- a) the Project Intellectual Property is identified, recorded and carefully distinguished from the outputs of other research;
 - b) prior to any publication of the results of the research, the Organisation shall identify (pursuant to Clause 10.6) whether patenting is appropriate and, where it is reasonable so to do, make applications for patents; and
 - c) all such applications are diligently prosecuted having regard to all relevant circumstances.
- 10.3 The Grantors require the Organisation to ensure that all persons in receipt of the Grantors' funding or working on a Grant-funded activity (including employees, students, visiting fellows, collaborators and subcontractors) are employed or services are engaged on terms that vest all Grant-funded IP in the Organisation.
- 10.4 Project Intellectual Property shall vest in the Organisation.
- 10.5 Not for profit organisations shall seek the prior written consent of the Grantors (not to be unreasonably withheld) to any commercial use of, or granting to any third party any exploitation rights over Project Intellectual Property. Such consent shall be sought by completing the consent application form available from www.wellcome.ac.uk/hicf. As a condition of granting consent, the Grantors will require the not for profit organisation to accept the then current standard revenue and equity sharing agreement for the Health Innovation Challenge Fund.
- 10.6 The Organisation shall grant (and shall procure that any collaborators grant) to the Grantors a perpetual worldwide, royalty free, non-exclusive and irrevocable licence to use or publish information or results from the research. However this licence does not include the right to exploit the results commercially.
- 10.7 If the Organisation does not protect, manage or exploit any Project Intellectual Property arising out of the Grant to the reasonable satisfaction of the Grantors, then the Grantors shall have the right, but not a duty, to protect, manage and exploit such Project Intellectual Property. Unless the Grantors reasonably consider that the opportunity to protect, manage or exploit such Project Intellectual Property for the public benefit could be lost and more immediate action is required, such right shall only be exercised six (6) months after the Grantors have given the Organisation notice in writing that it is failing to protect, manage and exploit such Project Intellectual Property to the Grantors' satisfaction. The Organisation agrees to do, and will ensure that its employees, students and any third party acting on its behalf do, all acts required to assist the Grantors in such protection and exploitation.
- 10.8 In addition to, or as an alternative to, the income sharing and/or equity sharing provisions of this clause 10, the DOH may opt for another method of receiving some or all of its return on the Grant. For example, where the Grant-funded Project results in the development of any products or services, the Exploiting Party or its licensees shall make such products OR such services available to the DOH for application in the treatment of NHS funded patients (whether by direct or indirect supply of such products or services or by granting of full paid-up licences or by other means) at a discounted price to the DOH. For example, the DOH

may receive free services such as training or maintenance, for application in the treatment of NHS funded patients, alongside products purchased under normal commercial terms or vice versa.

- 10.9 Where the DOH elects to receive some or all of its return in the form of Product Discounts then the Exploiting Party agrees to procure and provide the necessary financial information according to the principles of open book costing.
- 10.10 Where the DOH elects to receive all of its return in the form of Quasi-Equity or Product Discounts then the levels of Product Discounts or Quasi-Equity returns will be negotiated to be equivalent to the returns due under revenue or equity sharing as set out in Clauses 3.3 and 3.4 of the Revenue and Equity Sharing Agreement. The Organisation will provide the DOH with sufficient financial information including details of product and service sales forecasts to allow compliance with State Aid Legislation.

11. **LIMITATION OF LIABILITY**

- 11.1 The Grantors accept no responsibility or liability, financial or otherwise, for expenditure (or liabilities arising out of such expenditure) or liabilities arising out of the activities funded by the Grant. The Grantors will not indemnify the Organisation, any Grantholder or any other person working on the Grant (including employees, students, visiting fellows, collaborators and subcontractors) against any claims for compensation or against any other claims (whether under any statute or regulation or at common law) for which the Organisation may be liable as an employer or otherwise or for which any such person may be liable, including in respect of any termination or reduction in value of the Grant.

12. **INSURANCE**

- 12.1 Without prejudice to Clause 11, and if requested by the Grantors, the Organisation shall, throughout the duration of the Grant-funded Project, effect and maintain with a reputable insurance company a policy or policies of insurance providing an adequate level of cover in respect of all risks which may be incurred by the Organisation arising out of or in connection with the Organisation's performance of the Grant-funded Project.
- 12.2 If requested by the Grantors, the Organisation shall produce documentary evidence to demonstrate that any insurance policies pursuant to Clause 12.1 are in force.
- 12.3 The provisions or the amount of cover of any insurance shall not relieve the Organisation of any liabilities incurred by the Organisation. It shall be the responsibility of the Organisation to determine the amount of insurance that will be adequate to enable the Organisation to satisfy its liabilities in undertaking the Grant-funded Project.

13. **TRANSFER**

- 13.1 The Organisation shall promptly inform the Grantors if the Grantholder intends to transfer to another organisation. If that organisation is in the UK and is eligible to hold the Grant and is able to provide a suitable environment to enable the project to be successfully completed, the expectation is that the Grant would be transferred with the Grantholder, subject to (i) the written consent of the Grantors and (ii) written agreement from the Organisation and the receiving organisation. If suitable arrangements for transfer or continuation of the Grant funded Project cannot be agreed then the Grantors may terminate the Grant.
- 13.2 Grants will not be re-costed following any transfer pursuant to Clause 13.1. The unspent balance of Directly Incurred Costs funds and Exceptions funds, together with a pro rata share of Directly Allocated Costs funds and Indirect Costs funds, will be transferred to the new receiving organisation. The receiving organisation will be required to confirm to the Grantors that it will provide any balance of resources needed to complete the project.
- 13.3 The Organisation must consult the Grantors if it is proposed to change the Grantholder, for example following retirement, resignation or sickness. Where the Grantholder is transferring to another organisation in the UK and eligible to receive grants, the provisions of Clause 13.1 and 13.2 will apply. In other circumstances, the Organisation will nominate a replacement Grantholder. The Grantors shall determine in their sole discretion whether the nominated replacement meets the eligibility criteria and has the expertise and experience to lead the project to a successful conclusion. If the Grantors do not approve the nominated replacement then the Grantors may terminate the Grant.

14. GENERAL

- 14.1 The Grantors reserve the right to amend these Grant Conditions.
- 14.2 In the event of any conflict between the provisions of these Grant Conditions as amended from time to time, and of the Funding Agreement, the provisions of the Funding Agreement will take precedence.
- 14.3 The Organisation (or the Grantholders if appropriate) must inform the Grantors without delay of any change to the status of the Organisation or the Grantholders which might affect their ability to comply with these Grant Conditions.
- 14.4 The Grantholders must inform the Grantors as soon as practicable of any significant divergence from the original aims and directions of the research that is being funded by the Grant.
- 14.5 The Grantors reserve the right to terminate the Grant on notice with immediate effect.
- 14.6 The Grantors and the Organisation do not intend that any of these Grant Conditions should be enforceable by any third party.
- 14.7 These Grant Conditions shall be governed by and construed in accordance with English law. The Organisation and the Grantholders irrevocably submit to the jurisdiction of the English courts to settle any disputes in connection with these Grant Conditions.

15. DEFINITIONS

"Contract Documents" means these Grant Conditions, the Award Letter, and the Funding Agreement between the Grantors and the Organisation, the Wellcome Trust policies and positions on grants and the Department of Health policies on grants and any other documents recording the arrangements between the Parties with regard to the Grant

"Department of Health" or "DOH" means the Secretary of State for Health acting through the Department of Health

"Directly Allocated Costs"	means the costs of resources used by a project that are shared by other activities. Such costs 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
"Directly Incurred Costs"	means costs that are explicitly identifiable as arising from the conduct of a project and are charged as the cash value actually spent and supported by an audit record
"End of Grant Research Report"	means a form on which the Organisation reports on the activities funded by the Grant, which must be completed by the principal Grantholder and submitted to the Grantors within three months of the end of the Grant Period or as otherwise required by the Grantors
"End of Grant Spend Report"	means a form completed by the Organisation that must be submitted to the Grantors within two months of the end of the Grant Period or as otherwise required by the Grantors and that sets out: <ul style="list-style-type: none">(a) a comparison of (i) actual expenditure by the Organisation during the Grant Period of the Grant and (ii) the total amount awarded by the Grantors in respect of the Grant(b) an explanation for any variances between (i) and (ii) above, and(c) any further information that the Grantors request from the Organisation
"Exceptions"	means any Directly Incurred Costs which the Grantors fund at 100% of Full Economic Cost, subject to actual expenditure incurred, or items which are outside of Full Economic Cost
"Full Economic Cost"	Means, for higher education institutions only, a cost which, if recovered across an Organisation's full programme, would recover the total cost (Directly Allocated Costs, Directly Incurred Costs, Indirect Costs and total overhead) including an adequate recurring investment in the Organisation's infrastructure
"Funding Agreement"	means the funding agreement or convertible loan agreement , as appropriate, entered into between the Organisation and the Grantors in relation to the Grant the current form of which may be found at www.wellcome.ac.uk/hicf
"Grant"	means the grant or loan facility described in the Funding Agreement
"Grant Period"	means the period of the Grant set out in the Funding Agreement or the Award Letter, commencing on the start date confirmed by the Organisation in the manner indicated by the Grantors
"Grantholder and"	means the principal applicant (and any co-applicant, as specified in the Funding Agreement) who has

Grantholders"	responsibility for the leadership of the Grant funded research and for overall management of the research
"Grantors"	means the Department of Health and the Wellcome Trust Limited as trustee of the Wellcome Trust
"Indirect Costs"	means any non-specific costs charged across all projects based on estimates that are not included as Directly Allocated Costs. They include the costs of the Organisation's administration such as personnel, finance, library and some departmental services
"Intellectual Property" or "IP"	means (i) patents, designs, trademarks and trade names (whether registered or unregistered), copyright and related rights, database rights, Know-how and confidential information; (ii) all other intellectual property rights, in each case whether registered or unregistered and similar or equivalent rights anywhere in the world which currently exist or are recognised in the future; and (iii) all applications, renewals or extensions (including supplementary protection certificates) in relation to any such rights
"NHS Costs"	means NHS support costs, NHS treatment costs and NHS excess treatment costs
"Organisation"	means the company, university, NHS trust, institution, research council or other body at which some or all of the research funded by the Grant will be carried out or which employs the Grantholder(s) and which takes responsibility for the management of the research project and the accountability for Grant funds provided
"Product Discounts"	means discounts on the prices charged for products and services incorporating or derived from the Project IP
"Project"	means the research detailed in the Application to be undertaken by the Organisation and funded by the Grantors
"Project Intellectual Property"	means any Intellectual Property created, devised, or arising out of the Organisation's undertaking and performance of the Project or any part of it
"PubMed Central"	means a free digital archive of biomedical and life science journal literature operated by the National Center for Biotechnology Information, a division of the U.S. National Library of Medicine
"Quasi Equity"	means the issuing of loans, debentures or convertible debt from time to time in any company in consideration, or part consideration, of the assignment or grant of a licence or an option thereto to such company of any Project IP
"Spend Report"	means a form that must be completed by the Organisation and submitted to the Grantors that sets out: (a) a comparison of (i) actual expenditure by the Organisation during a particular period on a particular Grantors grant or (in the case of

Organisation Spend Reports), on all active Grantors grants held by an Organisation and (ii) the amount paid by the Grantors during that period in respect of that grant or (in the case of Organisation Spend Reports) in respect of all active Grantors grants held by an Organisation

- (b) an explanation for any variances between (i) and (ii) above, and
- (c) any further information that the Grantors request from the Organisation

"UK PubMed Central"

means a UK counterpart of PubMed Central developed by the Wellcome Trust and various funding partners

"Wellcome Trust"

means the Wellcome Trust (a charity registered in England with number 210183), acting through its trustee, The Wellcome Trust Limited (a company registered in England with number 2711000)