

**HEALTH INNOVATION CHALLENGE FUNDING AGREEMENT**

This Agreement is made on

2011 between the following parties

<b>A.</b>	<b>TRUST</b>	
	<b>Name:</b>	<b>THE WELLCOME TRUST LIMITED</b> , a company registered in England & Wales as Trustee of the Wellcome Trust, a charity registered in England under no. 210183 (the " <b>Trust</b> ")
	<b>Company no:</b>	2711000
	<b>Address:</b>	Technology Transfer, The Wellcome Trust, 215 Euston Road, London, NW1 2BE
	<b>Contact:</b>	Wellcome Technology Transfer
	<b>Tel:</b>	+44 (0)20 7611 8202
	<b>E-mail:</b>	techtransfer@wellcome.ac.uk
<b>B.</b>	<b>DEPARTMENT</b>	
	<b>Name:</b>	<b>THE SECRETARY OF STATE FOR HEALTH acting through the DEPARTMENT OF HEALTH</b> (the " <b>Department</b> ")
	<b>Address:</b>	Central Commissioning Facility, Grange House, 15 Church Street, Twickenham, TW1 3NL
	<b>Contact:</b>	Assistant Director, Health Innovation Challenge Fund
	<b>Tel:</b>	+44 (0)20 8843 8000
	<b>E-mail:</b>	[email]
<b>C.</b>	<b>ORGANISATION</b>	
	<b>Name:</b>	[name] (the " <b>Organisation</b> ")
	<b>Address:</b>	[address]
	<b>Contact:</b>	[contact]
	<b>Tel:</b>	[telephone]
	<b>E-mail:</b>	[email]

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**RECITALS:**

- (A) The Grantors have agreed in principle to make an award of £● (● pounds sterling) (the "Award Amount") to the Organisation to support a study entitled "[xx]".
- (B) The Parties have agreed that the Project (as defined below) shall be managed and carried out in accordance with the provisions of this Agreement.

**IT IS AGREED** as follows:**1. INTERPRETATION**

In this Agreement:

- 1.1 **"Agreement"** means this agreement;
- 1.2 **"Application"** means the application made by the Organisation for a grant under the Health Innovation Challenge Fund and attached at Schedule 1;
- 1.3 **"Award Amount"** has the meaning given in Recital A;
- 1.4 **"Award Letter"** means the letter from the Grantors specifying the amount of the Grant that has been awarded;
- 1.5 **"Background Intellectual Property"** means any Intellectual Property created, devised, generated, owned or licensed by the Organisation or to which the Organisation has rights prior to the Effective Date, which is necessary or useful for undertaking the Project or the protection or exploitation of the Project Intellectual Property, including without limitation **[list any specific patents]**;
- 1.6 **"Business Day"** means any day which is not a Saturday, Sunday or a bank holiday or public holiday in **[Scotland or]** England and Wales;
- 1.7 **"Commencement Date"** means the date of the last signature of this Agreement;
- 1.8 **"Conditions"** means the conditions set out at Schedule 2 **[(if any)]** which must be satisfied (to the reasonable satisfaction of the Grantors) at all times during the Project;
- 1.9 **"Confidential Information"** means any and all data, results, Know-How, show how, software, plans, details of research work, discoveries, inventions, intended publications, intended or pending patent applications, designs, technical information, business plans, budgets and strategies, business or financial information or other information in any medium and in any form, and any physical items, prototypes, compounds, samples, components or other articles or Materials disclosed on or after the Effective Date of this Agreement by one Party to another Party whether orally or in writing or in any other form;
- 1.10 **"Documents"** means reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROMs, computer programs and documents thereof, computer information storage means, samples of material, other graphic or written data and any other media on which Know-How can be permanently stored;
- 1.11 **"Drawdown Notice"** means a notice in writing signed by the Organisation as detailed in Schedule 8 of this Agreement;
- 1.12 **"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 two (2) months of the end of the Grant Period or as otherwise required by the Grantors;

- 1.13 **"End of Grant Spend Report"** means a form completed by the Organisation that must be submitted to the Grantors within three (3) months of the end of the Grant Period or as otherwise required by the Grantors and that sets out:
- a) a comparison of (i) actual expenditure by the Organisation during the Grant Period on 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;
- 1.14 **"Equity Holdings"** means any equity or other interest (whether by way of debenture, warrant, security or otherwise) in any company transferred or issued in consideration of the assignment or grant of a licence or an option thereto to such company in respect of any Project Intellectual Property;
- 1.15 **"Exploiting Party"** means one of the Organisation or the Grantors, being the Party responsible for commercialising and exploiting the Project Intellectual Property and/or the Background Intellectual Property in accordance with Clause 9 which shall be the Organisation, until the exercise of the option set out in Clause 9.7;
- 1.16 **"Grant"** means the grant funding to the Organisation by the Grantors, details of which are set out in the Award Letter and in Schedule 4;
- 1.17 **"Grant Conditions"** means the grant conditions for the Health Innovation Challenge Fund programme, as may be amended from time to time, a current copy of which is available from [www.wellcome.ac.uk/hicf](http://www.wellcome.ac.uk/hicf);
- 1.18 **"Grantholder and Grantholders"** means the Principal Investigator (and any co-applicant, as specified in the Award Letter) who has responsibility for the leadership of the Grant funded project and for overall management of the research;
- 1.19 **"Grantors"** means the Department and the Trust;
- 1.20 **"Grant Period"** means the period of the Grant set out in the Award Letter, commencing on the start date confirmed by the Organisation in the manner indicated by the Grantors;
- 1.21 **"Intellectual Property"** (or **"IP"**) means (i) patents, designs, trade marks 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;
- 1.22 **"IPMG"** means (if applicable) the intellectual property management group constituted in accordance with Schedule 6;
- 1.23 **"Know-How"** means any technical and other information which is not in the public domain, including information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, assays, research plans, procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), processes (including manufacturing processes, specifications and techniques), laboratory records, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries and information contained in submissions to and information from ethical committees and regulatory

authorities and computer programs or algorithms. Know-How includes Documents containing Know-How, including but not limited to any rights including trade secrets, copyright, database or design rights protecting such Know-How. The fact that an item is known to the public shall not be taken to preclude the possibility that a compilation including the item, and/or a development relating to the item, is not known to the public;

- 1.24 “**Material**” means any chemical or biological substance including any:
- (a) organic or inorganic element;
  - (b) nucleotide or nucleotide sequence including DNA and RNA sequences;
  - (c) gene;
  - (d) vector or construct including plasmids, phages or viruses;
  - (e) host organism including bacteria, fungi, algae, protozoa and hybridomas;
  - (f) eukaryotic or prokaryotic cell line or expression system or any development strain or product of that cell line or expression system;
  - (g) protein including any peptide or amino acid sequence, enzyme, antibody or protein conferring targeting properties and any fragment of a protein or a peptide enzyme or antibody;
  - (h) drug or pro-drug;
  - (i) assay or reagent;
  - (j) any other genetic or biological material or micro-organism;
  - (k) data for the derivation of molecular structures including NMR spectra, X Ray diffraction patterns and other primary experimental information, assignments and other calculations required for determination of the structure, and co-ordinates of the derived molecular structure; and
  - (l) transgenic animals;
- 1.25 “**Milestones**” means the milestones set out at Schedule 3 which must be met to the reasonable satisfaction of the Grantors by the Milestone Dates in order for further tranches of the Award Amount to be released;
- 1.26 “**Milestone Dates**” means the dates set out in Schedule 3 for the achievement of the Milestones;
- 1.27 “**Organisation**” means the organisation named at the head of this Agreement at which some or all of the Project will be carried out and which takes responsibility for the management of the Project and accountability for the Grant provided;
- 1.28 “**Parties**” means the parties to this Agreement, or any of them, as the context may require and “**Party**” shall be interpreted accordingly;
- 1.29 “**Policies and Positions**” means the policies and positions of the Grantors for grants from time to time, which are set out at <http://www.dh.gov.uk> and <http://www.wellcome.ac.uk>;
- 1.30 “**Principal Investigator**” means [name of researcher] of the Organisation;

- 1.31 **"Project"** means the research entitled "[title]" (as more particularly detailed in the Application) to be undertaken by the Organisation and funded by the Grantors under the terms of this Agreement;
- 1.32 **"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;
- 1.33 **"Project Inventions"** means any inventions created, devised or arising out of the Organisation's undertaking and performance of the Project or any part of it;
- 1.34 **"Project Start Date"** means the date upon which the Organisation commences work on the Project, as agreed in writing between the Grantors and the Organisation;
- 1.35 **"PubMed Central"** means an archive of life science journal literature operated by the National Center for Biotechnology Information, a division of the US National Library of Medicine accessible at <http://www.pubmedcentral.nih.gov>;
- 1.36 **"Research Steering Group"** or **"RSG"** means (if applicable) the group constituted in accordance with the provisions set out in Schedule 5;
- 1.37 **"Site Visit Group"** means the group constituted in accordance with Clause 7;
- 1.38 **"Staff"** means all scientific and technical staff who are employees, students, officers, contractors, independent consultants, visiting researchers or otherwise of the Organisation and who participate in the Project including the Principal Investigator and [names of other key researchers]; and
- 1.39 **"Treasury Policy"** means a policy which outlines what type of bank deposit or treasury instruments the Organisation's funds can be held in and which typically also states the minimum ratings of banks with which funds can be deposited (e.g. Standard and Poor's).
- 1.40 The Schedules and Recitals are incorporated in and form part of this Agreement and any reference to this Agreement shall include the Schedules and Recitals.
- 1.41 In this Agreement: (a) the masculine gender shall include the feminine and neuter and the singular number shall include the plural and vice versa; (b) references to persons shall include bodies corporate, unincorporated associations, partnerships and individuals.
- 1.42 The headings in this Agreement are inserted for convenience only and shall not affect the construction of the provision to which they relate.
- 1.43 Any phrase introduced by the terms "including", "include", "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.
- 1.44 Where reference is made in this Agreement to the prior written consent of the Grantors being required in respect of any matter, the Organisation shall give not less than twenty (20) Business Days notice to the Trust of the matter for which such consent is required.
- 1.45 Reference to any statute, statutory instrument, regulation, bylaw or other requirement of English law and to any English legal term for any actions, remedy, method of judicial proceeding, legal document, legal status, court, official or any legal concept or doctrine shall, in respect of any jurisdiction other than England, be deemed to include that which most nearly approximates in that jurisdiction to the relevant legal term.
- 1.46 Reference to the winding up of a person include the amalgamation, reconstruction, reorganisation, administration, dissolution, liquidation, bankruptcy, merger or consolidation of such person and an equivalent or analogous procedure under the law of any jurisdiction in which that person is incorporated, domiciled or resident or carries on business or has assets.

1.47 The rights of the Grantors may be exercised individually or jointly.

## 2. USE OF FUNDING

2.1 The Grantors and the Organisation agree that the Project, the Project Intellectual Property and the Background Intellectual Property and associated matters shall be governed in accordance with this Agreement, the Award Letter, the Grant Conditions and the Policies and Positions. If there is any conflict between the provisions of this Agreement and the Award Letter, Grant Conditions or the Policies and Positions, then the provisions of this Agreement and the Award Letter shall prevail.

## 3. MILESTONE PAYMENTS

3.1 The Award Amount will be payable in tranches as follows:

Tranche	Amount of Advance	Payable:
1	£●	Within 20 Business Days of the Commencement Date
2	£●	On achievement of Milestone One in accordance with Clause 3.3
3	£●	On achievement of Milestone Two in accordance with Clause 3.3
4	£●	Within 20 Business Days of acceptance of an End of Grant Research Report by the Grantors in accordance with Clause 4.2

3.2 The Grantors shall pay the first tranche of the Grant to the Organisation within 20 Business Days of the Commencement Date. The Project shall be commenced within six (6) months of the Commencement Date.

3.3 When the Organisation considers that any of the Milestones have been achieved by the relevant Milestone Date:

- a) The Organisation shall as soon as reasonably practicable send a detailed report (the "**Milestone Report**") to the Grantors evidencing how the relevant Milestone has been achieved and a Drawdown Notice requesting payment of the next tranche of the Grant;
- b) The Grantors shall confirm to the Organisation in writing, within twenty (20) Business Days of receipt by the Grantors of the Milestone Report and a Drawdown Notice either that:
  - i) the Milestone has been achieved by the Milestone Date to the Grantors' reasonable satisfaction, in which case, the Grantors shall make payment of the next tranche of the Grant within twenty (20) Business Days of the date of such written confirmation in the amounts set out in this Agreement; or
  - ii) the Milestone has not been achieved to the Grantors' reasonable satisfaction by the relevant Milestone Date and that the payment shall not take place, in which case the Grantors shall provide the Organisation with reasonable details of the grounds on which they have reached this decision.

- 3.4 The Grantors may, at their sole discretion, grant the Organisation a reasonable period of time ("**Milestone Extension**"), in order to address the reasons why the Grantors have judged that a particular Milestone has not been met. Upon the expiry of a Milestone Extension, the Grantors shall, at their sole discretion, decide whether or not to permit full or partial payment of the relevant tranche of funding to the Organisation.
- 3.5 The final tranche of the Grant will be paid within twenty (20) Business Days of receipt by the Organisation of the Grantors' acceptance of the End of Grant Research Report in accordance with Clause 4.2.
- 3.6 All payments due to the Organisation under this Agreement shall be made in pounds sterling. Payment shall be made by electronic wire transfer of immediately available funds directly to the Organisation's account designated below or to any other account which the Organisation may specify by written notice.

Bank Account for the Organisation:

Account Name:	[	]
Account No.:	[	]
Bank:	[	]
Sort code:	[	]
SWIFT code:	[	]
Branch:	[	]

- 3.7 The Grantors shall not be under any obligation to pay any part of the Grant to the Organisation if, at the time of request by the Organisation, (i) any of the events described in Clause 13.1 has occurred or (ii) if so requested by the Grantors, the Organisation has failed to submit its Treasury Policy for the Grantors' review or the Treasury Policy fails to provide the Grantors with adequate assurance over the security of the funds to be provided.

#### 4. **REPORTING**

- 4.1 The Organisation shall make reports on work being carried out under the Project to the Grantors in accordance with the Grant Conditions and this Agreement.
- 4.2 The Organisation shall complete and submit an End of Grant Research Report on the form provided by the Grantors (at [www.wellcome.ac.uk/hicf](http://www.wellcome.ac.uk/hicf)) within two (2) months after completion of the Project or at such other time as may be agreed with the Grantors. The Grantors will evaluate the End of Grant Research Report and will notify the Organisation within [thirty (30)] Business Days of receipt whether the report is acceptable to the Grantors. If the End of Grant Research Report is not acceptable to the Grantors, each of the Grantors shall notify the Organisation of its reasons which may include that the report is incomplete or insufficiently detailed.
- 4.3 Up to ten per cent (10%) of the Award Amount, subject to a maximum amount of one hundred thousand pounds sterling (£100,000) (the "Retained Amount") shall be retained by the Grantors until the receipt of an End of Grant Research Report acceptable to the Grantors in accordance with Clause 4.2. The Retained Amount will be paid to the Organisation within twenty (20) Business Days of receipt by the Organisation of the Grantors' acceptance of the End of Grant Research Report.
- 4.4 Within three (3) months following completion of the Project, the Organisation shall complete and submit an End of Grant Spend Report to the Grantors in the form provided by the Grantors (at [www.wellcome.ac.uk/hicf](http://www.wellcome.ac.uk/hicf)). For the avoidance of doubt, it is a requirement that the financial information in this report must be presented with reference only to the currency in which the Award Amount was advanced by the Grantors.

#### 5. **PROJECT STAFF AND CONDUCT**

- 5.1 The Organisation warrants that it has or that it shall have in place contracts with its Staff such that any Project Intellectual Property shall vest in the Organisation. The Grantors may upon reasonable notice require the Organisation to produce all and any Staff contracts for inspection by the Grantors.
- 5.2 The Organisation shall cause to be kept full, detailed and accurate records of all of its activities and results obtained in connection with the Project. In this respect, the Organisation shall and shall procure that the Staff shall at all times:
- (a) observe professional standards; and
  - (b) keep scientific notebooks recording all research, development and other work carried out in respect of the Project and the results of such research, development and other work, including keeping bound note books with page numbering recording all results and observations signed by the persons obtaining such results or making such observations, and countersigned appropriately.
- 5.3 The Organisation shall be responsible for the management, monitoring and control of all research work undertaken by it. This shall include, as appropriate, the requirements of all applicable laws and regulatory authorities, including those governing the use of radioactive isotopes, diagnostic tools, animals, pathogenic organisms, genetically modified organisms, toxic and hazardous substances, research on human subjects and human embryos, and shall also include appropriate ethical approvals and consents, including such approvals and consents for obtaining human tissues and other relevant human samples. For any clinical trial carried out pursuant to the Project, the Organisation shall on the Grantors' written request supply details of such clinical trial for publication on the Trust's clinical trials register and the NIHR CRN portfolio database.
- 5.4 The Organisation shall upon request make available to the Grantors [and/or the RSG] copies of all records generated in connection with the Project, including for the avoidance of doubt, records generated by its Staff under Clause 5.2 and by any third parties working on the project pursuant to Clause 8.
- 5.5 The Organisation shall ensure that data reported to the Grantors [and/or the RSG] which are relevant to the progress of the Project are reliable, accurate and not misleading.
- 5.6 The Organisation shall procure that the Principal Investigator monitors the work carried out under the Project for material that may be the subject of Project Inventions and shall promptly notify the [Organisation and Grantors] [RSG and IPMG] of any such Project Inventions. [Without prejudice thereto, the Organisation shall make reports on work being carried out under the Project to the RSG each quarter, or from time to time as the RSG may reasonably request.]
6. **PROJECT MANAGEMENT**
- 6.1 [Subject to Clause 6.2] The Principal Investigator shall be responsible for the overall management of the Project and for ensuring that the Project is administered in accordance with this Agreement.
- 6.2 [The Grantors and the Organisation shall establish a Research Steering Group to oversee the Project, as detailed in Schedule 5.]
- 6.3 [The Organisation shall appoint a project manager from its Staff who shall be responsible on a day-to-day basis for co-ordinating the internal and external components of the Project.]
7. **SITE VISIT GROUP**
- 7.1 Either of the Grantors may take the lead in appointing a Site Visit Group, made up of a small team of independent experts, and observers from the Trust's Technology Transfer Division and/or the Department of Health's NIHR Central Commissioning Facility. The Organisation shall ensure that the Site Visit Group shall have reasonable access during

normal working hours and at mutually agreed times to visit the premises where the Project is being conducted to consult informally with the Organisation's Staff working on the Project, to evaluate progress, performance and key issues and to report back to the Grantors [and the RSG] on its findings.

7.2 The Site Visit Group may recommend that the Grantors terminate the Project due to a serious failure in the progress, management or conduct of the Project (including a finding that the Project will be unable to achieve the next Milestone within a reasonable time period after the relevant Milestone Date), or due to a major external scientific, technical or commercial barrier which means that the Project is unlikely to succeed in its objectives. If the Site Visit Group makes such a recommendation pursuant to this Clause 7.2, the Grantors may terminate this Agreement pursuant to Clause 13.2b.

7.3 The Grantors may, in their sole discretion, allow the Organisation a reasonable period of time to take corrective action to address any failings identified by the Site Visit Group (if such failings are capable of correction). If the Grantors grant the Organisation a period of time to correct such failings and the Organisation does not correct such failings within the period specified by the Grantors (if any), the Grantors shall retain the right to terminate this Agreement pursuant to Clause 13.2b.

## 8. PROJECT COLLABORATORS AND SUBCONTRACTORS

8.1 If the Organisation wishes to use a third party collaborator or sub-contractor to conduct any part of the Project, it shall seek the consent of [the RSG] [the Grantors] unless such sub-contractor or collaborator is specified in the Application. The Organisation shall ensure in all cases that any collaborations or sub-contracts are on the following terms:

- a) That the third party shall not have any rights to any results emerging from such work, and all such results shall as between the Parties and the third party be deemed to be Project Intellectual Property and owned in accordance with the provisions of this Agreement;
- b) That the third party shall be under obligations of confidence concerning such results on terms equivalent to those set out under this Agreement;
- c) That the third party shall keep detailed records including scientific notebooks of all of its activities and upon request shall make available copies to the Grantors;
- d) That the third party will upon reasonable request make available its employees and/or consultants for discussion with the Site Visit Group [and/or RSG] as referred to in Clause 7 [and Schedule 5]; and
- e) That the provisions of such sub-contract or collaboration agreement shall be consistent with the milestone nature of the Award and the termination provisions of this Agreement, and shall terminate if this Agreement terminates.

## 9. INTELLECTUAL PROPERTY – OWNERSHIP, PROTECTION AND MANAGEMENT

9.1 If any Project Intellectual Property arises, it shall be the property of the Organisation. In accordance with paragraph 10 of the Grant Conditions, the Organisation shall be responsible for the identification, protection, management and exploitation of the Project Intellectual Property to achieve public benefit. If the Organisation fails to do so, the Grantors shall have the right but not the obligation to do so.

9.2 The Organisation 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](http://www.wellcome.ac.uk/hicf). As a condition of granting consent, the Grantors will require the Organisation to accept the

then current standard revenue and equity sharing agreement for the Health Innovation Challenge Fund, the current version of which is available from [www.wellcome.ac.uk/hicf](http://www.wellcome.ac.uk/hicf).

9.3 In accordance with clause 10 of the Grant Conditions, the Department may opt to receive its share of any revenue or equity as discounted products or services.

9.4 The Organisation shall make the Background Intellectual Property available for use in the Project and for the protection or exploitation of the Project Intellectual Property. Unless otherwise agreed in writing with the Grantors, the Organisation shall retain responsibility for filing, prosecuting, maintaining, defending, and enforcing protection for the Background Intellectual Property at its own cost. If the Organisation wishes to cease doing so in relation to any of the Background Intellectual Property, it shall notify the Grantors and the Grantors shall have the right but not the obligation to take over responsibility for the Background Intellectual Property. The Organisation shall not grant any rights to any third parties over the Background Intellectual Property without the prior written consent of the Grantors.

9.5 If required to do so by the Grantors, the Organisation shall establish an IPMG in accordance with the provisions of Schedule 6.

9.6 The Organisation shall use its reasonable efforts to manage the commercialisation and exploitation of the Project Intellectual Property.

9.7 The Organisation accepts that in order to exploit the Project Intellectual Property, it may be necessary or useful to grant a licence to the Background Intellectual Property and at the request of the Grantors (where a Grantor is the exploiting party) shall grant such a licence (to the extent that this does not conflict with any pre-existing third party rights). Any such licence grant shall be non-exclusive, and only to the extent necessary or useful to exploit the Project Intellectual Property.

9.8 If the Organisation:

(a) is subject to any of the events listed in Clause 13.1(c);

(b) has failed to maintain, protect, defend or enforce the Project Intellectual Property or any part of it where it is reasonable to do so and where the Grantors have expressly advised the Organisation to do so;

(c) notifies the Grantors in writing that it has decided at any time not to exploit any Project Intellectual Property; or

(d) does not protect, manage or exploit any Project Intellectual Property to the reasonable satisfaction of the Grantors (including if after five (5) years since its creation any Project Intellectual Property has not been commercially exploited by the Organisation),

then the Grantors shall have the right, but not the obligation, to protect, manage and exploit such Project Intellectual Property and/or to have the Project Intellectual Property assigned to either of them by the Organisation in whole or in part (at the Grantors' request) and the Organisation undertakes at the request of the Grantors and at its own cost to do (or to procure others to do) everything necessary for vesting in the Grantors the full benefit of such Project Intellectual Property to be transferred to it under this Agreement. Unless the Grantors reasonably consider that the opportunity to protect, manage or exploit the Project Intellectual Property for the public benefit could be lost and that 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 the Project Intellectual Property to the Grantors' satisfaction.

9.9 For the avoidance of doubt, if either of the Grantors do exploit the Project Intellectual Property, the Organisation shall procure that the Principal Investigator and other members of its Staff who contributed to the creation of Project Intellectual Property (and

any third party acting on its behalf) do all acts required to assist the Grantors in relation to the commercialisation and exploitation of the Project Intellectual Property and (if applicable) the Background Intellectual Property, including:

- (a) executing any necessary documents;
- (b) assisting in the transfer of Know-How generated in the course of the Project to a third party licensee or corporate vehicle; or
- (c) co-operating in any litigation of any dispute relating to the Project Intellectual Property.

Any such exploitation by either of the Grantors shall be subject to the provisions of the revenue sharing agreement set out at [www.wellcome.ac.uk/hicf..](http://www.wellcome.ac.uk/hicf..)

9.10 If any exploitation of the Project Intellectual Property results in the acquisition of any Equity Holding (for example, but without limitation, because the Project Intellectual Property is assigned or licensed to a corporate vehicle spun out of the Organisation) then the following principles shall apply:

- a) the Exploiting Party shall take the lead in connection with the finding of potential investors and in negotiation of the transaction resulting in the Equity Holding;
- b) the Exploiting Party shall require at its discretion either (i) observer status for meetings of the board of directors (including the right to receive copies of board minutes and board papers), or (ii) actual board membership;
- c) the Parties acknowledge that it would be advantageous for the board of directors and any scientific advisory board to include external representation, such representation to incorporate business, pharmaceutical and scientific expertise [and to be chosen by or in conjunction with the IPMG], and shall use reasonable endeavours to include such representation; and
- d) the Organisation accepts that it will have to assign or license the Project Intellectual Property into such a corporate vehicle.

9.11 The Non-Exploiting Party agrees that it shall pass to the Exploiting Party immediately any or all exploitation opportunities that it becomes aware of from time to time in connection with the Project Intellectual Property. The Non-Exploiting Party further undertakes that it shall not engage in any activities (including in relation to the Background Intellectual Property) that could reasonably lead to the loss of an exploitation opportunity without the prior written consent of the Exploiting Party.

## 10. **AUDIT**

10.1 The Organisation shall procure that the control of expenditure to be funded under the Grant is governed by the normal standards and procedures of the Organisation and is covered by the formal audit arrangements that exist in the Organisation. The Grantors shall have the right 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 that 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 may require the Organisation to provide them with relevant extracts from the letter.

10.2 The Organisation shall provide access to accounting and other financial records relating to the Grant and the activities funded by it for auditors and other personnel from or appointed by the Grantors at any time (at the Grantors' expense), if requested. Such access shall include the right to inspect any equipment or facilities acquired or funded

under the Grant. Where elements of expenditure under the Grant have been subcontracted, the Organisation shall ensure that the rights of access extend to the accounts and records of any such subcontractor.

- 10.3 The Grantors shall have the right, each at its individual discretion and expense, to audit (either directly or via third parties engaged by it) the Grant and the income and expenditure on the activities funded by the Grant and/or the systems used by the Organisation to administer the Grantors' grants generally during normal business hours. For this purpose the Grantors and their agents and advisors may inspect and take copies of all relevant books of accounts and records.
- 10.4 The Organisation shall maintain a separate accounting cost code specific to the Grant, and all costs and income properly relating to the Award shall be accounted for through that cost code. The Organisation shall ensure that appropriate records are kept to support the entries made on the cost code.
- 10.5 The Organisation acknowledges and agrees that pursuant to Clause 3 of the Grant Conditions, references to an audit by the Department includes any audit by the National Audit Office or Audit Commission.

## 11. PUBLICATIONS AND ANNOUNCEMENTS

- 11.1 The Grantors acknowledge the Organisation's need to publish details of the results of the Project in learned journals and to present such results at academic conferences. So as not to jeopardise any Project patent filing or exploitation being carried out by the Exploiting Party (in any case where the Exploiting Party is not the Organisation), the Organisation shall procure that the Principal Investigator furnishes the Exploiting Party [and the IPMG] with copies of any proposed publication or presentation which relates to any Project Intellectual Property in advance of the submission of such proposed publication or presentation to a journal, editor or publication. The Exploiting Party and the IPMG shall have twenty (20) Business Days from and including the date of receipt from the Organisation of any proposed publication or presentation to object to the same because there is patentable subject matter relating to a Project Invention that needs protection or such publication would materially jeopardise any exploitation activity. The Exploiting Party shall not seek to withhold consent where such publication or presentation will not prejudice the protection or exploitation of the Project Intellectual Property.
- 11.2 If the Exploiting Party [or the IPMG] object to any such publication or presentation on the basis that it would disclose patentable information, the Organisation shall refrain (and shall procure that the Principal Investigator and the Staff also refrain) from making such publication or presentation for a period of forty (40) Business Days from the date of receipt of such objection in order for the Exploiting Party to file the relevant patent application(s) with respect to the patentable subject matter contained in the proposed publication or presentation.
- 11.3 A copy of the final manuscript of all research publications that relate to the Project must be deposited into PubMed Central (or UK PubMed Central) upon acceptance for publication, to be made freely available as soon as possible and in any event no later than six (6) months after the journal publisher's official date of final publication.
- 11.4 Save as required by law or any competent regulatory authority, no announcement concerning this Agreement or its subject matter shall be made by the Organisation without the prior written approval of the Grantors. For the avoidance of doubt the Organisation and the Principal Investigator must consult with the Grantors (and the relevant media office as directed by the Grantors) on any press statements that may be issued about the Project or any findings from the Project.

## 12. CONFIDENTIALITY

- 12.1 Subject to Clauses 12.2 to 12.8 (inclusive) each Party undertakes that both during this Agreement and for a period of five (5) years after its termination, it shall keep confidential and not disclose to any person (other than to its officers, employees, consultants or professional advisors whose province it is to know), any Confidential Information of another Party disclosed to or obtained by it in connection with this Agreement. Each Party shall take all reasonable security precautions in relation to the Confidential Information under its control.
- 12.2 The Organisation shall only disclose the Confidential Information to those of its Staff (together with its administrative or technology transfer staff involved in monitoring the Project) who need to know it strictly for the purposes of the Project and the administration of the Grant, provided that they are bound by confidentiality and non-use obligations in respect of such Confidential Information and are first made aware of the Organisation's confidentiality obligations towards the Grantors.
- 12.3 If the Organisation considers it necessary for the purpose of the Project to disclose the Confidential Information to employees, officers, students, visiting academics, contractors, sub-contractors, independent consultants or third parties who are not members of the Organisation's Staff undertaking the Project, then before any such disclosure takes place the Organisation shall procure that each of the persons concerned are bound by confidentiality and non-use obligations in respect of such Confidential Information and are first made aware of the Organisation's confidentiality obligations.
- 12.4 If the Organisation is not the Exploiting Party, the Exploiting Party shall be entitled to disclose any Confidential Information of the Organisation or Confidential Information generated during the Project if it is reasonably necessary or desirable to do so in order to protect or exploit the Project Intellectual Property.
- 12.5 Without prejudice to Clause 12.1, and save in the case of publication in which case the provisions of Clause 11 shall apply, the Parties shall each use reasonable endeavours to keep details of any Project Inventions confidential pending filing of a patent application claiming such Project Invention.
- 12.6 Clause 12.1 shall not apply to:
- (a) information which is or was already known to the receiving party at the time of disclosure under this Agreement, as shown by the receiving party's written records, without any obligation to keep it confidential;
  - (b) information which is independently developed by employees, officers, students, visiting academics, contractors, sub-contractors, independent consultants or third parties of the receiving Party who are not members of the Organisation's Staff undertaking the Project and who have not had access to the Confidential Information of the disclosing Party;
  - (c) information which at the time of being disclosed or obtained by the receiving party under this Agreement or at any time thereafter, is published or otherwise generally available to the public other than due to default by the receiving party of its obligations hereunder;
  - (d) the disclosure of information by the Grantors for the purposes of publishing summary details of awards made by the Grantors consisting of the name of the Organisation, the name of the Principal Investigator, the title of the Project and the amount of the Award or (in the event that the Project includes a clinical trial) for the purpose of registering a clinical trial on the Trust's clinical trial register or the NIHR CRN portfolio database;
  - (e) the disclosure to a Party's professional advisers or to the Grantors' Site Visit Group of information reasonably required to be disclosed for purposes relating to this Agreement, or

- (f) information which is required to be disclosed by a competent Court or regulatory authority or otherwise by applicable law (including any requirements for disclosure under the Freedom of Information Act 2000 (“FOIA”)), provided that where it is free to do so, the receiving party shall give notice of such disclosure as soon as reasonably practicable. Where such disclosure of information is required under the FOIA from the Organisation and such information relates to the Trust or the Department, the Organisation shall notify the applicable Party within five (5) Business Days of receiving an information request that such a request has been made and the details thereof. The Organisation shall allow five (5) Business Days to consult with and, to the extent permitted by law, shall take into account any representations made by either the Trust or the Department before such information is disclosed to the requestor and shall on request provide an update of the status of the Organisation’s response and the information that it is intending to disclose.
- 12.7 Each Party shall ensure that all personnel and third parties to whom Confidential Information of another Party is disclosed are informed of the provisions of Clauses 11 (Publications and Announcements) and Clause 12 (Confidentiality).
- 12.8 [The Parties acknowledge that the information contained or listed in Schedule 7 is information which the Parties reasonably consider is exempt from disclosure under the FOIA on the basis that it is confidential and/or commercially sensitive information, which if disclosed without the prior consent of the Party to which the information relates, would, or would be likely to breach confidentiality and/or prejudice the commercial interests of that Party.]
- 12.9 Nothing in this Agreement shall prevent the Grantors disclosing any Confidential Information for the purpose of any examination pursuant to Section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Grantors have used their resources.
- 12.10 The Parties acknowledge and agree that the National Audit Office has the right to publish a brief outline of this Agreement in its relevant reports to Parliament.
- 12.11 Where a Party considers that an Organisation is holding information that it requires in order to comply with its obligations under the FOIA or the Environmental Information Regulations (“EIRs”), the Party holding such information 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, on the request and at no charge to the Party that it requires such information in order to comply with its obligations under FOIA or the EIRs and in any case within five (5) Business Days.

### 13. DURATION AND TERMINATION

- 13.1 In addition to the termination rights under the Grant Conditions, the Grantors or the Organisation shall have the right to terminate this Agreement forthwith at any time by giving written notice of termination to the other Party (“Defaulting Party”), upon the occurrence of any of the following events:
- a) the Defaulting Party commits a breach of a material obligation set out in this Agreement which is not capable of remedy;
  - b) the Defaulting Party commits a breach of a material obligation set out in this Agreement which is capable of remedy but has not been remedied within sixty (60) days of the receipt by it of a notice from the other Party identifying the breach and requiring its remedy;
  - c) if the Defaulting Party is subject to any of the following, or any similar events in any jurisdiction:

- i) goes into liquidation or passes a resolution for voluntary winding up or its directors convene a meeting of shareholders to consider passing such a resolution (except for the exclusive purpose of amalgamation or bona fide reconstruction not involving insolvency and in such manner that the entity resulting therefrom effectively agrees to be bound by or assumes the obligations imposed on that other party under this Agreement);
  - ii) has an encumbrancer take possession of or an administrative receiver or receiver or similar officer appointed over all or any part of its assets or undertaking; or an application is made for the appointment of an administrative receiver, receiver or similar officer over all or any part of its assets or undertaking;
  - iii) has an administrator appointed (by court order or otherwise (including without limitation by its directors or by a floating charge holder)), or has an application made either for the appointment of an administrator or for an administration order, or has a notice of intention to appoint an administrator given;
  - iv) is the subject of any judgment or order made against it which is not complied with or discharged within 30 days or is the subject of any execution, distress, sequestration or other process levied upon or enforced against any of its assets;
  - v) has proposed in respect of it a company voluntary arrangement pursuant to the Insolvency Act 1986 or any other composition or scheme or arrangement with or assignment for the benefit of any of its creditors;
  - vi) has a petition presented for its winding up (which is not dismissed within 14 days of its service) or has an application made for the appointment of a provisional liquidator or has a creditors' meeting convened pursuant to s 98 Insolvency Act 1986;
  - vii) ceases or threatens to cease to carry on business; or
  - viii) is or becomes unable to pay its debts as they fall due, suspends making payments on any of its debts or, by reason of actual or anticipated financial difficulties commences negotiations with one or more of its creditors with a view to rescheduling any of its indebtedness;
- d) the Defaulting Party is prevented from performance of its obligations by an event of force majeure (as defined in Clause 16.1) for more than six (6) months.

13.2 In addition, the Grantors shall be entitled to terminate this Agreement by notice in writing to the Organisation if:

- (a) the Organisation fails to comply with any of the Conditions (if any are set); or
- (b) the Site Visit Group recommends termination of the Project in accordance with Clause 7 and the Organisation fails to correct any identified failings within the time period granted by the Grantors (if any) under Clause 7.3.

13.3 If the Principal Investigator ceases to be involved with the Project, ceases to be employed by or provide services to the Organisation, ceases to carry out research at premises controlled by the Organisation, or is prevented through illness or injury from promptly fulfilling his obligations under it, the Grantors shall consult with the Organisation

to ascertain whether the Project or its progress will be jeopardised by such event. If in the reasonable opinion of the Grantors:

- (a) such event will jeopardise the Project or its progress, the Grantors may terminate this Agreement by written notice; or
- (b) the Project has reached a stage such that the services of the Principal Investigator are not key to the completion of the Project, the Grantors and the Organisation shall negotiate in good faith any amendments necessary to this Agreement so as to enable the satisfactory completion of the Project within a reasonable time.

13.4 Termination of this Agreement howsoever arising shall be without prejudice to the rights and duties of any Party accrued prior to termination. The clauses in this Agreement which expressly or impliedly have effect after or notwithstanding termination (including Clauses 1, 2, 5, 6, 9, 10, 12 and 14) shall continue to be enforceable notwithstanding termination.

13.5 Upon termination prior to the end of the Project, the Organisation shall return any part of the Grant funds received from the Grantors under this Agreement which is unspent at the date of termination (after deduction of reasonable, properly incurred non-cancellable commitments incurred prior to the date of termination, the Organisation being under a duty to mitigate such commitments as far as is reasonably practicable to do so).

#### 14. **WARRANTIES AND LIABILITY**

14.1 The Organisation warrants that:

- (a) it has the requisite authority to enter into this Agreement;
- (b) it has full power and authority to assume all of its obligations under this Agreement;
- (c) to the best of its knowledge and belief:
  - i) it is either the legal and beneficial owner of all right, title and interest in and to the Background Intellectual Property, or has a licence to use the Background Intellectual Property for the purposes of the Project and to the extent necessary to meet its obligations under this Agreement;
  - ii) it will be the legal and beneficial owner of all right, title and interest in and to the Project Intellectual Property;
  - iii) it has not granted any third party any right in respect of the Project Intellectual Property (other than in accordance with the provisions of this Agreement), and has not charged or encumbered and will not charge or encumber any of the same;
  - iv) it has not itself nor through any of its Staff disclosed to any third party (other than under appropriate confidentiality obligations) any Confidential Information relating to the Project, nor is it obliged to do so;

and

(d) it has in respect of all licensed in Background Intellectual Property the warranties from the owner or licensor (as the case may be) of that Intellectual Property that are equivalent of those set out in Clause 14.1 (c).

14.2 Except as expressly provided in this Agreement, none of the Parties gives any warranties or makes any representations with respect to any of the Project Intellectual Property and/or Background Intellectual Property or any products derived from them, or their fitness for any purpose, or that any material produced or supplied by any Party and any processes or techniques used, proposed or recommended by any Party will not infringe any patent or other Intellectual Property rights of any person in any country.

- 14.3 Subject to Clause 14.5, the maximum liability of any one Party to any of the other Parties arising out of this Agreement shall not exceed the Award Amount.
- 14.4 Except in circumstances of fraud or wilful misconduct by a Party or its affiliates, no Party or any of its affiliates shall be liable to another Party or any affiliate of another party for special, indirect, incidental or consequential damages, whether in contract, warranty, negligence, tort, strict liability or otherwise, arising out of any breach of or failure to perform any of the provisions of this Agreement.
- 14.5 Nothing in this Agreement shall limit the liability of any Party in respect of:
- (a) personal injury or death arising out of that party's negligence or wilful misconduct; or
  - (b) fraud or fraudulent misrepresentation.

## 15. **ESCALATION AND DISPUTE RESOLUTION PROCEDURE**

- 15.1 If any dispute arises out of or in connection with this Agreement then any Party may give a notice that a dispute exists (a "Dispute Notice") to the other Parties and if the Parties (or the RSG) have not resolved the dispute within ten (10) Business Days of the date of the Dispute Notice, the Parties shall escalate such dispute to the Director of Technology Transfer at the Trust, the Director General of Research and Development at the Department and [enter title of official] at the Organisation (collectively, the "Executive Officers") and the respective Executive Officers shall use reasonable endeavours to resolve the dispute as soon as is reasonably practicable but in any case by ten (10) Business Days of the date at which the dispute was escalated to them.
- 15.2 If the Executive Officers of the Parties are not able to resolve a dispute referred to them pursuant to Clause 15.1, the Parties will, at the request of any of them, attempt in good faith to resolve the dispute through an agreed Alternative Dispute Resolution ("ADR") procedure.
- 15.3 If the matter has not been resolved by an agreed ADR procedure within twenty (20) Business Days of the initiation of such procedure, any Party may bring proceedings in accordance with Clause 17.12. For the avoidance of doubt, any Party may apply to the court for an injunction whether or not any issue has been escalated under Clause 15.

## 16. **FORCE MAJEURE**

- 16.1 In the event that any Party is delayed or prevented from the performance of its obligations under this Agreement by an event of force majeure, the obligations of the Parties shall remain in suspense during the continuation of the force majeure event (subject to Clause 13.1(d)). Force majeure events shall mean any event outside of the reasonable control of a Party and include, without limitation, riot, sabotage, acts of war or piracy, fire, flood, storm, earthquake, epidemic or pandemic, delay caused by failure of power supply or transport.

## 17. **GENERAL**

- 17.1 This Agreement, together with the Award Letter, the Application and any revenue and equity sharing agreement entered into pursuant to Clause 9 constitute the entire agreement and understanding between the Parties relating to the subject matter of this Agreement and together they supersede and replace all prior drafts, previous understandings, arrangements, representations or agreements, whether in writing or oral, between the Parties relating to the subject matter of this Agreement.
- 17.2 No Party shall be deemed to have waived any of its rights or remedies under this Agreement unless the waiver is expressly made in writing and signed by a duly authorised representative of that Party. In particular, no delay or failure of any party in exercising or enforcing any of its rights or remedies under this Agreement shall operate as a waiver of those rights or remedies nor shall any single or partial exercise or

enforcement of any right or remedy by any Party preclude or impair any other exercise or enforcement of that right or remedy by that Party.

- 17.3 The Parties shall not make any press or other public announcement concerning any aspect of this Agreement without first obtaining the agreement of the other Parties to the text of that announcement, such agreement not to be unreasonably withheld or delayed, save that the Grantors shall be permitted to publish summary details of the Project including the name of the Principal Investigator, the name of the Organisation, the title of the Project, the Award Amount and the following description of the Project:

**[Grantors to insert web paragraph here]**

- 17.4 Nothing in this Agreement shall give rise to any partnership or the relationship of principal and agent between the Grantors and the Organisation.

- 17.5 Any notice to be given pursuant to this Agreement shall be in writing in the English language and shall be delivered by personal service, overnight courier, by registered, recorded delivery or certified mail (postage prepaid) to the address or facsimile number of the recipient Party set out below or such other address or facsimile number as a Party may from time to time designate by written notice to the other Parties. Any notice by facsimile shall be confirmed by the sender sending a confirmatory copy of the notice by registered, recorded delivery or certified mail (postage prepaid). The Parties agree that email is not a valid method of giving notice under this Agreement.

**Address of the Organisation**

[enter postal address]

Fax No: [enter fax number]

For the attention of: [enter contact name]

**Address of the Trust**

Technology Transfer Division  
The Wellcome Trust Limited  
215 Euston Road  
London NW1 2BE

Fax No: +44 (0)20 7611 8857

For the attention of: The Contracts Officer

With a copy to: Dr Tim Knott

**Address of the Department**

Central Commissioning Facility  
Grange House  
15 Church Street  
Twickenham  
TW1 3NL

Fax No: +44 (0)20 8843 8001

For the attention of: The Assistant Director, Health Innovation Challenge Fund

With a copy to: The Director, Central Commissioning Facility

- 17.6 Any notice given pursuant to Clause 17.5 shall be deemed to have been received:

- (a) in the case of personal service, delivery by courier or sending by certified mail, on the day of receipt, provided receipt occurs on a Business Day of the recipient Party or otherwise on the next following Business day of the recipient; or
  - (b) in the case of facsimile, on acknowledgement by the recipient facsimile receiving equipment on a Business Day if the acknowledgement occurs before 5:00pm local time of the recipient Party and in any other case on the following Business Day
- 17.7 None of the rights or obligations under this Agreement may be assigned or transferred without the prior written consent of the other Parties. This Agreement shall be binding on and take effect for the benefit of the successors in title of the Parties.
- 17.8 If any provisions of this Agreement are held to be invalid, illegal or unenforceable (in whole or in part) such provisions or parts shall to that extent be deemed not to form part of this Agreement but the remainder of this Agreement shall continue in full force and effect.
- 17.9 This Agreement does not create any right enforceable by any person not a party to it under the Contracts (Rights of Third Parties) Act 1999.
- 17.10 Each Party shall at its own cost do and execute or procure to be done and executed all necessary acts, deeds, documents and things reasonably within its power to give effect to this Agreement.
- 17.11 Each Party shall do and execute or arrange for the doing or executing of all acts, documents and things as may be necessary in order to implement this Agreement.
- 17.12 This Agreement shall be governed by and construed in accordance with English law. The Parties irrevocably submit to the exclusive jurisdiction of the English courts provided that nothing in this clause shall prevent any Party from seeking injunctive relief in any court of competent jurisdiction in respect of a breach or threatened breach of Clause 12 (confidentiality).

**IN WITNESS** whereof the Parties or their duly authorised representatives have executed this Agreement on the date written at the head of this Agreement.

For and on behalf of

**The Wellcome Trust Limited as trustee of The Wellcome Trust**

Signed:

Signed:

Name:

Name:

Date:

Date:

For and on behalf of

**The Secretary of State for Health** acting  
through the **Department of Health**

Signed:

Name:

Date:

For and on behalf of

**[Organisation]**

Signed:

Name:

Date:

[For and on behalf of

**[Organisation]**

Signed:

Name:

Date:

Read and understood by the Principal Investigator who is not personally a party to this Agreement:

.....

SPECIMEN

**SCHEDULE 1**

**The Application**

SPECIMEN

## SCHEDULE 2

### Conditions

1. [Compliance with the Organisation's obligations with respect to the formation and operation of the RSG in accordance with Schedule 5].
2. [Engagement and involvement of an independent industry adviser to the RSG with relevant experience in accordance with [Schedule 5]].
3. Co-operation with the Site Visit Group prior to and during visits in accordance with Clause 7.
4. [Timely consultation with the IPMG on patent strategy and patent prosecution in accordance with Clause [11 ] and Schedule 6].

[If none applied – state none]

SPECIMEN

**SCHEDULE 3**

**Milestones**

Milestone	Description of Milestone	Milestone Date
1		[x] months from the Project Start Date
2		[x] months from the Project Start Date
3		[x] months from the Project Start Date

SPECIMEN

**SCHEDULE 4**

**Costs Schedule**

***[Grantors to insert budget table from Award Letter]***

SPECIMEN

**SCHEDULE 5****The Research Steering Group**

- 1 The Grantors and the Organisation shall establish a Research Steering Group (“**RSG**”) to oversee the Project, which shall:
- (a) monitor the performance and technical content of the Project against the Plan;
  - (b) assess the ongoing results of the Project and what has been learnt and agree future research;
  - (c) critically assess the results of the Project;
  - (d) identify and address any weaknesses or delays in the Project;
  - (e) co-ordinate internal and outsourced components of the Project, including agreeing any collaborations or sub-contracts not specifically identified in the Plan;
  - (f) modify or authorise modifications to the implementation of the Project (including the implementation of the Project objectives) as necessary from time to time;
  - (g) operate as the key forum through which the Grantors and the Organisation shall be informed as to progress of the Project and through which the Grantors shall liaise with the Organisation concerning the conduct of the Project, including preparing an annual written report for the Grantors on progress; and
  - (h) advise the Organisation when and whether each of the research phases, Milestones or targets of the Project have been achieved,
- provided that the RSG shall have no right to amend or vary the provisions of this Agreement or to alter the fundamental scope of objectives of the Project which power is reserved to the Parties.
- 2 The RSG shall be established and run by the Parties as follows:
- (a) The RSG shall be comprised of the following persons (“**Members**”):
    - (i) the Principal Investigator(s);
    - (ii) at least one independent industry adviser with experience which is relevant to the Project;
    - (iii) one representative of the Organisation’s technology transfer office (at the Organisation’s option); and
    - (iv) two (2) representatives or nominees of the Grantors (at the Grantors’ option) from the Trust’s Technology Transfer Division and/or the NIHR Central Commissioning Facility.
  - (b) Each of the Grantors shall have the option to appoint one (1) Member, to remove any Member appointed by it and to appoint any person to fill a vacancy arising from the removal or retirement of such Member. If either of the Grantors does not appoint such a Member, it shall have the right to receive all papers that a Member would be entitled to receive.

- (c) The Organisation shall have the option to appoint one Member from its technology transfer office, to remove any Member appointed by it and to appoint any person to fill a vacancy arising from the removal or retirement of such Member.
- (d) The Organisation and the Grantors shall agree jointly on the identity of the other Members. The costs and expenses of the independent industry adviser(s) shall be met out of the Award Amount.
- (e) The Principal Investigator shall be the chairperson of the RSG ("**RSG Chair**") and shall be responsible for organising meetings of the RSG, including preparing papers prior to meetings and ensuring that minutes of meetings are produced promptly after each meeting. All papers and minutes shall be circulated to each Member in a timely manner. Except in exceptional circumstances (when the Principal Investigator may nominate another person as his alternate), the Principal Investigator shall attend all RSG meetings.
- (f) The quorum for RSG meetings shall be three (3) Members including a Member appointed by one of the Grantors, the Principal Investigator and at least one of the independent industry advisers. Decisions of the RSG shall be made by majority agreement of the Members present. The RSG Chair shall not have a casting vote. If the RSG is unable to reach agreement on a decision, the decision shall be escalated to the Director of Technology Transfer at the Trust, the Director of the NIHR Central Commissioning Facility and [suitably senior representative of Organisation] for resolution.
- (g) Meetings of the RSG shall be convened by the Principal Investigator as required but at least once every three (3) months (or less frequently with the consent of the Grantors) during the Project, on not less than ten (10) Business Days' written notice (to be accompanied by an agenda for the meeting and a report on the progress of the Project). Following the end of the Project, the RSG shall meet within twenty (20) Business Days to discuss and report on the outcomes of the Project.
- (h) Any or all Members may, with the prior consent of the RSG Chair, attend a meeting of the RSG by telephone or other electronic means rather than in person, provided that all Members attending the meeting can hear and be heard for all parts of the meeting. For the avoidance of doubt, RSG Members attending a meeting by telephone or other electronic means shall have the same voting rights as an RSG Member present in person.
- (i) A representative from any key outsourcing suppliers, collaborators or subcontractors involved in the Project (if any) shall be invited to RSG meetings as an observer. The RSG shall also have power to invite persons whose special skills or influence might advance the Project to attend and address meetings of the RSG. Such persons shall not be Members of the RSG and shall not have a right to participate in its decision-making process. The RSG Chair shall ensure that any such invitees sign confidentiality agreements in a form acceptable to all parties.

**[SCHEDULE 6]****The Intellectual Property Management Group (IPMG)**

- 1 The Organisation and the Grantors shall establish an IPMG, which shall:
  - (a) approve all public disclosures relating to the Project, including presentations, posters and papers (provided that the contribution of the Grantors is acknowledged in all such publications and quoting the Award number);
  - (b) identify new inventions arising out of the Project and make recommendations for IP strategy, including patent filing and prosecution strategy and assessment of freedom to operate issues; and
  - (c) approve the Exploiting Party's commercialisation and translation strategy in relation to the Project Intellectual Property.
- 2 The IPMG shall be established and run by the Parties as follows:
  - (a) The IPMG shall be comprised of the following persons ("**IPMG Members**"):
    - (i) the Principal Investigator;
    - (ii) an independent adviser appointed by mutual agreement between the Grantors and the Organisation;
    - (iii) one representative of the Organisation's technology transfer office or its nominee; and
    - (iv) no more than two (2) representatives of the Grantors' departments dealing with technology transfer or their nominees.
  - (b) Each of the Grantors shall have the option to appoint one (1) IPMG Member, to remove any IPMG Member appointed by it and to appoint any person to fill a vacancy arising from the removal or retirement of such IPMG Member. In the event that either of the Grantors does not appoint such IPMG Members, it shall have the right to receive all papers that an IPMG Member would be entitled to receive.
  - (c) The Organisation shall have the option to appoint one IPMG Member from the Organisation's Technology Transfer office, to remove any IPMG Member appointed by it and to appoint any person to fill a vacancy arising from the removal or retirement of such IPMG Member. If the Organisation does not appoint such an IPMG Member, the Organisation shall have the right to receive all papers, which an IPMG Member would be entitled to receive. The costs and expenses of the independent industry adviser(s) shall be met out of the Award Amount.
  - (d) The Principal Investigator shall chair the IPMG ("**IPMG Chair**") and shall be responsible for organising meetings of the IPMG, including preparing papers prior to meetings and ensuring minutes of meetings are produced. All papers and minutes shall be circulated to each IPMG Member in a timely manner.
  - (e) The quorum for IPMG meetings shall be two (2) IPMG Members, provided that at least one is an IPMG Member appointed by the Organisation and at least one is an IPMG Member appointed by one of the Grantors. Decisions of the IPMG shall be made by majority agreement of the persons present. The IPMG Chair shall not have a casting vote. If the IPMG is unable to reach agreement on a decision, the decision shall be escalated to Director of Technology Transfer at the Trust, the Head of Intellectual Property of NIHR Central Commissioning Facility and **[Head of**

Organisation's Technology Transfer office] for resolution. If the IPMG Chair is unable to attend an IPMG meeting, the Organisation and the Grantors shall, in good time before the meeting, nominate an alternative IPMG member to act as Chair.

- (f) Meetings of the IPMG shall be convened by the IPMG Chair at least once per year and otherwise on an "as needed" basis, either in person at the premises of the Organisation or by 'virtual private network' videoconference if necessary. Any or all IPMG Members may, with the prior consent of the IPMG Chair, attend a meeting of the IPMG by telephone or other electronic means rather than in person, provided that all IPMG Members attending the meeting can hear and be heard for all parts of the meeting. For the avoidance of doubt, IPMG Members attending a meeting by telephone or other electronic means shall have the same voting rights as an IPMG Member present in person

SPECIMEN

[SCHEDULE 7]

**[Commercially Sensitive Information]**

SPECIMEN

**SCHEDULE 8**

**Drawdown Notice**

[Organisation]  
[Address]  
[Address]  
[Address]

The Contracts Officer  
Technology Transfer Division  
The Wellcome Trust Limited  
215 Euston Road  
London NW1 2BE

[Date]

Dear Sirs

**The Funding Agreement (the “Agreement”) made on [ ] 201[•] between [Organisation] and The Wellcome Trust Limited as trustee of the Wellcome Trust and The Secretary of State for Health acting through The Department of Health.**

We refer to Milestone [number] as described in Schedule [•] of the Agreement and hereby confirm the completion of the achievement of such Milestone. A report detailing achievement of Milestone [number] [is attached to this letter]/[has been provided to the Grantors].

Please confirm that Milestone [number] has been achieved to your reasonable satisfaction and that we may proceed to drawdown [•] Pounds Sterling (£[•]) in respect of the [number] tranche of the Award Amount in the instalments set out at Schedule [•] of the Agreement.

Terms and expressions defined in the Agreement shall have the same meanings in this Letter.

Yours faithfully

.....  
For and on behalf of  
**[Organisation]**