

RESEARCH CONTRACT

BETWEEN

THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE (1)

AND

[INSERT] (2)

Version number: NIHR ODA standard research contract v9/18

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SECTION 1: FORM OF CONTRACT

This agreement is made on [DATE] by and between:

- (1) **THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE** of 39 Victoria Street, Westminster, London, SW1H 0EU acting as part of the Crown ("the **Authority**"); and
- (2) [INSERT] of [INSERT] ("the **Contractor**")

who may, from time to time, be hereinafter referred to individually as the "**Party**" or collectively as the "**Parties**".

IT IS AGREED THAT:

- 1. The Contractor shall use the funding provided under this Contract to undertake a research project entitled [PROJECT TITLE] in accordance with the work specified in Section 3, being project application [PROJECT REFERENCE], dated [PROPOSAL DATE], [AMENDING CORRESPONDENCE, INSERT DATE], 3 (the "**Research**").
- 2. On condition that the Contractor complies with the terms of this Contract, the Authority will pay the Contractor the Approved Cost as set out in Section 4 in respect of: (i) undertaking the Research in accordance with this Contract; and (ii) the Contractor's assignment of copyright and rights in the nature of copyright in the Report to the Authority on behalf of the Crown pursuant to Clauses 14 and 17 of Section 2.
- 3. This Form of Contract (Section 1) together with its Schedules and the attached Sections 2 to 6 inclusive are the documents which collectively form the "**Contract**" (as defined in Section 2).
- 4. The Contract effected by the signing of this Form of Contract constitutes the entire agreement between the Parties relating to the subject matter of the Contract and supersedes all prior negotiations, representations or understandings.

SIGNED:

For the Authority:

SIGNATURE

FULL NAME

.....

POSITION HELD ON BEHALF OF THE AUTHORITY

.....

DATE

.....

SIGNED:

For the Contractor:

SIGNATURE

FULL NAME

.....

POSITION HELD ON BEHALF
OF THE CONTRACTOR

.....

DATE

.....

SECTION 2: TERMS AND CONDITIONS

- 1. DEFINITIONS AND INTERPRETATION**
- 2. COMMENCEMENT AND DURATION**
- 3. ADMINISTRATION AND DIRECTION OF RESEARCH**
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- 15. SITE VISIT GROUP**
- 16. INTELLECTUAL PROPERTY RIGHTS**
- 17. EXPLOITATION OF INTELLECTUAL PROPERTY**
- 18. DUTY OF CARE**
- 19. NIHR FACULTY**
- 20. TERMINATION UPON OCCURRENCE OF EVENTS**
- 21. CONSEQUENCES OF TERMINATION**
- 22. EQUIPMENT**
- 23. FORCE MAJEURE**
- 24. WARRANTIES AND LIABILITY**
- 25. INSURANCE**
- 26. ASSIGNABILITY**
- 27. SEVERABILITY**
- 28. WAIVER**
- 29. CORRUPT GIFTS OR PAYMENTS**
- 30. FRAUD**
- 31. DISPUTE RESOLUTION**
- 32. NOTICES**
- 33. RELATIONSHIPS**
- 34. FREEDOM OF INFORMATION ACT 2000**
- 35. TRANSPARENCY**

- 36. UNLAWFUL DISCRIMINATION**
- 37. ODA**
- 38. SAFEGUARDING PROVISIONS**
- 39. EVALUATION**
- 40. FURTHER ASSURANCE**
- 41. CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999**
- 42. LAW**

1. DEFINITIONS AND INTERPRETATION

1.1. As used in this Contract the following terms and expressions shall have the meaning shown below:

“Applicable Law”	means: <ul style="list-style-type: none">(a) any law, statute, regulation, byelaw or subordinate legislation in force from time to time to which a party is subject and/or in any jurisdiction that the Research is provided to or in respect of;(b) the common law and laws of equity as applicable to the parties from time to time;(c) any binding court order, judgment or decree; any applicable direction, policy, rule or order that is binding on a party and that is made or given by any regulatory body having jurisdiction over a party or any of that party’s assets, resources or business.
“Application”	means the application dated [.....] and made by the Contractor for an NIHR ODA Global Health Research funding award.
"Approved Cost"	means the funding to be paid by the Authority to the Contractor for the Research in accordance with this Contract, being in the sum set out in Section 4.
“Arising Know How”	means Know How that is created, devised or generated by or on behalf of any of the Contractor or a Collaborator in the course of the performance of the Research.
"Authority's Representative"	means a person authorised to represent the Authority in respect of this Contract as identified in Section 5.
"Background IP"	means any Intellectual Property in existence at the Commencement Date or created, devised or generated other than in the performance of the Research and which is actually used in the performance of the Research.
“Business Day”	means a day other than Saturday, Sunday and bank holidays in London.
“Chief Investigator”	means the individual named in Section 5 or his/her successor(s).
"Collaborator"	means a person or organisation who works with the Contractor in connection with the Research on a collaborative basis. Such person or organisation shall not be a Sub-contractor.
“Collaborator Background IP”	means any Background IP: <ul style="list-style-type: none">(a) owned by the relevant Collaborator or to

which the relevant Collaborator has rights;
and/or

- (b) created, devised or generated by the relevant Collaborator's staff (including visiting researchers) working on Research during the term of the Research

and in each case which is used in the performance of the Research.

"Commencement Date"

means [.....] notwithstanding the last day of signature of this Contract.

"Commercial Use"

means any use that supports the generation of revenue including but not limited to:

- (a) any use in support of an application for regulatory approval for a product or service;
- (b) any use in support of the development, promotion or use of a product or service that will be made available on a fee paying basis;
- (c) any use in support of the development, promotion or provision of Health Care direct to an individual on a fee paying basis;
- (d) the provision of a product or a service to any Health Service Body or to any patient under the care of a Health Service Body or in any territory served by any Collaborator.

"Completion Date"

means [.....]

"Confidential Information"

means information of any form, however conveyed and irrespective of the media on which it is stored, that is:

- (a) information which has been designated as confidential by either Party; or
- (b) information that reasonably ought to be considered as confidential including information which relates to the business, affairs, properties, assets, trading practices, goods/services, developments, trade secrets, Intellectual Property, Know How, personnel, customers and suppliers and commercial sensitive information of either Party; or
- (c) Personal Data and/or sensitive personal data within the meaning of the Data Protection Act 1998; or
- (d) the Research Data.

"Contract"

means the contract concluded between the Parties, consisting of the following Sections:

Section 1 : Form of Contract

Section 2 : Terms and Conditions (including all Schedules

Section 3 : Research

Section 4 : Financial Arrangements

Section 5 : Key Staff

Section 6: Milestone Reporting Schedule

"Contractor Background IP"

means any Background IP or Know How:

- (a) owned by the Contractor or to which the Contractor has rights ; and/or
- (b) created, devised or generated by the Contractor's staff (including visiting researchers) working in the research group of and/or supervised by the Chief Investigator during the term of the Research

and in each case which is used in the performance of the Research.

"Contractor's Representative"

means the person to represent the Contractor in respect of this Contract as identified in Section 5.

"Crown"

means the government of the United Kingdom (including the governments of Northern Ireland, Scotland, and Wales), including, but not limited to, government ministers, government departments, government agencies and particular bodies.

"DAC"

means the Development Assistance Committee of the OECD.

"Data Controller"

has the meaning ascribed to it in the Data Protection Legislation.

"Data Processor"

has the meaning ascribed to it in the Data Protection Legislation.

"Data Protection Legislation"

means any Applicable Law relating to the processing, privacy, and use of Personal Data, as applicable to the performance of the Research from time to time.

"FOIA"

means the Freedom of Information Act 2000 and any subordinate legislation made under this Act from time to time together with any guidance and/or codes of practice issued under this Act or by the Information Commissioner in relation to such legislation.

"Foreground IP"

means any Intellectual Property that is created, generated or developed (whether in whole or in part) during the course of and for the purpose of any part of the Research. For the avoidance of

doubt, this:

- (a) includes Foreground IP generated by or on behalf of the Contractor or any Collaborator in the course of performing the Research; and
- (b) excludes Arising Know How and Research Data; and
- (c) excludes Intellectual Property that has been generated by the Contractor or any Collaborator without support from the NIHR.

“Fraud”

means any offence under English law or equivalent local laws creating offences in respect of fraudulent acts or at common law in respect of fraudulent acts in relation to the Contract, the facilitation or performance of the Research, or, defrauding or attempting to defraud or conspiring to defraud the Crown.

“IP Policy”

means the policy to be prepared by the Contractor and approved by the Authority in accordance with clause 16.1.

“Good Industry Practice”

means standards, practices, methods and procedures conforming to the law and the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged in a similar type of undertaking under the same or similar circumstances.

“Health Care”

has the meaning ascribed to it in section 64 of the Health & Social Care Act 2012 and includes both health care and social care provided to individuals on a non-fee paying basis. For the avoidance of doubt, Health Care is deemed to include (but is not limited to) evaluation, training and teaching purposes relating to the provision of care and treatment.

“Health Service Body”

has the meaning ascribed to it in section 9 of the National Health Service Act 2006.

“IATI Standard”

means the International Aid Transparency Initiative Standard.

“Health Research Authority Approval”

means the approval process for all study types within the NHS in England that brings together the assessment of governance and legal compliance undertaken by the Health Research Authority with the independent Research Ethics Committee opinion provided through the UK Health Departments’ research ethics service. Further detail, which may be amended from time to time,

is available on the Health Research Authority website.

“Insolvency Event”

means where a Party:

- (a) 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 there from effectively agrees to be bound by or assumes the obligations imposed on that other party under this Contract);
- (b) has an encumbrance take possession of 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 a receiver or similar officer over all or any part of its assets or undertaking;
- (c) 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;
- (d) is the subject of any judgment or order made against it which is not complied with or discharged within thirty (30) days or is the subject of any execution, distress, sequestration or other process levied upon or enforced against any of its assets;
- (e) has proposed in respect of it a company voluntary arrangement pursuant to the Insolvency Act 1986 or any other composition or scheme for the benefit of any of its creditors;
- (f) has a petition presented for its winding up (which is not dismissed within fourteen (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 section 98 of the Insolvency Act 1986;
- (g) ceases or threatens to cease to carry on

business;

- (h) is or becomes unable to meet its debts as they fall due within the meaning of section 123 of the Insolvency Act 1986; or

anything analogous to any of the events in (a) to (h) inclusive shall occur in relation to the Party under the law of any jurisdiction in relation to which it is subject.

"Intellectual Property" ("IP")

means all patents, rights to inventions, copyright and related rights, trademarks and trade names, rights to goodwill or to sue for passing off, rights in designs, database rights, rights in confidential information and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

"Key Staff"

means the persons named in Section 5.

"Know How"

has the meaning given to it in Commission Regulation (EU) 316/2014 of 21 March 2014 at Article 1, 1(i).

"NIHR"

means the National Institute for Health Research.

"OECD"

means the Organisation for Economic Co-operation and Development.

"ODA"

means Official Development Assistance, including ODA administrative costs, as defined by the OECD from time to time.

"Patient Benefit"

means achieving any one or more of the following:

- (a) identifiable improvements in the quality of treatment and clinical care offered in any territory served by any Collaborator or by any Health Service Body in England;
- (b) identifiable improvements in the experience of patients receiving care in any territory served by any Collaborator or from any Health Service Body in England;
- (c) identifiable improvements in patient health outcomes;
- (d) identifiable improvements in the efficiency of clinical or public health services in any territory served by any Collaborator or any Health Service Body in England;
- (e) identifiable and measurable cost savings achieved in any territory served by any

Collaborator or by any Health Service Body in England;

(f) generating revenue for any Health Service Body in England;

(g) or any other outcome that has been accepted in writing by the Authority and that is designed to benefit clinical or public health services in any territory served by any Collaborator or any Health Service Body in England or a significant number of patients receiving Health Care from any Health Service Body in England.

“Personal Data”	has the meaning ascribed to it in the Data Protection Legislation.
“Quarter”	means 1 April to 30 June, 1 July to 30 September, 1 October to 31 December, and 1 January to 31 March each year.
“Reports”	means any report, executive summary, paper, abstract or other document provided by the research team under this Contract pursuant to Clauses 13 and 14 and Section 6. For the avoidance of doubt this does not extend to Arising Know How, Research Data, Foreground IP or other Intellectual Property described therein.
“Reporting Milestone”	means the reporting dates set out at Section 6 which must be met by the Contractor to the reasonable satisfaction of the Authority by the Reporting Milestone Dates.
“Reporting Milestone Date”	means the dates set out in Section 6 for the achievement of the Reporting Milestone.
“Research”	means the programme of work to be undertaken by the Contractor that will be funded by monies paid under this Contract outlined in Section 3.
“Research Data”	means information or data which is not Personal Data that is collected or generated in the performance of the Research and includes (but is not limited to) information that is collated or stored in searchable form. For the avoidance of doubt, Research Data does not include information that has been analysed.
“Research Ethics Committee Reference Number”	means the number allocated to the trial by the National Research Ethics Service.
“Research Period”	means the period commencing on the Commencement Date and ending on the Completion Date or such later date as may be agreed between the Parties unless otherwise

	determined in accordance with the terms of the Contract.
“Site Visit Group”	means the group constituted in accordance with Clause 15.
“Sub-contract”	means a contract between two or more suppliers at any stage of remoteness from the Contractor in a sub-contracting chain, made wholly or substantially for the purposes of the Contractor performing (or contributing to the performance) of the whole or any part of this Contract.
“Sub-contractor”	means a party to a Sub-contract other than the Contractor.
"Variation"	means a variation to this Contract agreed and executed in accordance with Clause 6.

1.2. The interpretation and construction of this Contract shall be subject to the following provisions:

- 1.2.1. the interpretation of a reference to any statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the statute, enactment, order, regulation or instrument as subsequently amended or re-enacted;
- 1.2.2. references to Clauses, Sections and Schedules are to clauses, sections and schedules to this Contract. where the context allows, references to male gender include the female gender and the neuter, and the singular includes the plural and vice versa;
- 1.2.3. references to a Party shall include that Party's personal representatives, successors or permitted assignees;
- 1.2.4. general words are not to be given a restrictive meaning because they are followed by particular examples, and any words introduced by the terms "including", "include", "in particular" or any similar expression will be construed as illustrative and the words following any of those terms will not limit the sense of the words preceding those terms; and
- 1.2.5. the headings in this Contract are for convenience only and shall not affect its interpretation.

2. COMMENCEMENT AND DURATION

- 2.1. This Contract shall commence on the Commencement Date and, subject to earlier termination in accordance with its terms, shall continue in full force and effect until the Completion Date.
- 2.2. The Authority shall carry out a review of the Contractor's work relating to the Research at **[[2][3][6] [[two][three][six]]** months from the Commencement Date as set out in Section 6. As a result of the findings of this review, the Authority shall either:
 - 2.2.1. confirm the continuation of the Contract for the remaining term; or
 - 2.2.2. terminate this Contract without further liability by giving the Contractor notice in accordance with Clause 20.6.

3. ADMINISTRATION AND DIRECTION OF RESEARCH

- 3.1. Research commissioned by the Authority is open and, subject to the provisions of this Contract, details of Research are normally published.
- 3.2. The Authority may publish non-confidential details of the Research and the actual or projected costs of the Research.
- 3.3. The Contractor shall ensure that:
 - 3.3.1. each member of staff (whether a member of staff of the Contractor or any Collaborator) engaged on the Research is contractually obliged to observe the terms of this Contract and any further or supplementary contract entered into between the Parties hereto; and
 - 3.3.2. all such members of staff are advised promptly of any changes in the scope of this Contract or the Research.
- 3.4. Notwithstanding the provisions of Clause 20, the Authority may terminate this Contract in accordance with Clause 20.3 herein if any of the Key Staff is not available to fulfil their part in the Research for any part of the Research Period, subject to prior discussion with the Contractor to first attempt to identify a mutually acceptable replacement.
- 3.5. The objectives and general timeline of the Research are set out in Section 3. Within such objectives details of the exact programme of work to be followed and the day-to-day responsibility for carrying out this programme of work, the Research will be under the control of the Contractor, in consultation, as appropriate, with the Authority's Representative. The Contractor must ensure that the Research is:
 - 3.5.1. primarily relevant to near-term or long-term benefits to the health or prosperity of low or middle income countries as defined by the OECD from time to time;
 - 3.5.2. performed in accordance with the Authority's policy on the provision of ODA as published and updated from time to time; and
 - 3.5.3. performed and administered in particular (but without limitation) in accordance with the conditions applicable to ODA funding as set out by OECD guidance as published and updated from time-to-time (e.g. Is it ODA? Factsheet November 2008).
- 3.6. The Authority reserves the right to terminate this Contract in accordance with Clause 20.3 herein should the Contractor be unable or unwilling for any reason to continue with the Research or if in the reasonable opinion of the Authority the Contractor is consistently failing to achieve an acceptable standard in relation to the Research. In the event that the Authority elects to terminate the Contract pursuant to this Clause 3.6, such termination shall be without liability and no financial compensation whatsoever shall be payable by the Authority to the Contractor.
- 3.7. The Contractor shall provide the Research in accordance with the provisions of this Contract and establish and implement best practice and associated benefits.
- 3.8. The Contractor will use all reasonable endeavors to comply with guidance and advice on informatics initiatives which may be issued by the Authority from time to time.
- 3.9. The Contractor shall, and shall procure that the Collaborator(s) shall, for the duration of the Research, maintain information relating to the gender of their staff

and report these to the Authority as requested.

- 3.10. Subject to Clause 3.13, the Contractor shall put in place with each Collaborator participating in the Research a Collaboration Agreement consistent with Schedule D and the IP Policy (as approved by the Authority in accordance with Clause 16.1). The Contractor shall ensure that: (i) each Collaborator is obliged to comply with or fulfill requirements that are the same as or equivalent to the relevant provisions of this Contract; and (ii) each Collaborator accepts and will comply with the IP Policy. In addition to the requirements recorded at Clause 16.2, each Collaboration Agreement must explicitly record that each Collaborator:
- 3.10.1. acknowledges the terms of this Contract and the IP Policy;
 - 3.10.2. agrees to assist the Contractor in complying with the terms of this Contract and the IP Policy;
 - 3.10.3. agrees to comply with those aspects of this Contract and the IP Policy that are relevant to the Collaborator.
- 3.11. The relevant provisions of this Contract referred to at Clause 3.10 and that the Contractor shall procure that each Collaborator shall comply with, include, but are not limited to:
- 3.11.1. IP ownership and management provisions at Clauses 8 (Publicity, Publication and Branding), 9 (Confidentiality), 11 (Rights to Research Data), 16 (Intellectual Property Rights), 17 (Exploitation of Intellectual Property);
 - 3.11.2. research administration provisions at Clauses 3 (Administration and Direction of Research), 7 (Staff Appointments), 10 (Data Protection), 12 (Research Practice and Ethics), 18 (Duty of Care), 19 (NIHR Academy), 22 (Equipment), 24.1 (Warranties), 29 (Corrupt Gifts and Payments), 30 (Fraud), 35 (Transparency), 37 (ODA) and 38 (Safeguarding); and
 - 3.11.3. reporting provisions at Clauses 13 (Monitoring and Reporting), 14 (Final Report and Research Outputs Information) and 15 (Site Visit Group).
- 3.12. The Contractor shall be responsible for the acts and omissions of each Collaborator as though they were its own.
- 3.13. The Contractor shall submit to the Authority for review, comment and approval any proposed Collaboration Agreement in accordance with Section 6. From the date of submission of the draft copy by the Contractor, the Authority shall be entitled, within thirty (30) days, to require reasonable amendments to the Collaboration Agreement to the extent necessary for compliance with this Contract.

4. ACCOUNTING AND PAYMENTS

- 4.1. Payments will be made by the Authority during the Research Period in accordance with dates and amounts specified in Section 4. The Authority may suspend or reduce its payment of amounts due under Section 4 at any time if in the view of the Authority:
- 4.1.1. reasonable progress on the Research has not been maintained; or
 - 4.1.2. reports have not been submitted as required under Clauses 13, 14 and

Section 6; or

- 4.1.3. the Contractor has substantially failed to comply with the terms of this Contract (including where the Contractor has failed to procure that the Collaborator(s) comply with obligations as required by this Contract).
- 4.2. Subject to the terms of this Contract the Contractor is free to administer the funds paid in accordance with Section 4 within the terms of this Contract without further reference to the Authority.
- 4.3. Pursuant to Clause 4.1 payment suspensions may be lifted and if required a new payment schedule may be issued subject to the Authority's reasonable opinion that the issue(s) triggering the suspension being resolved in a timely manner. Any new payment schedule will account for any missed payments or payment reductions in lieu of the suspension if in the reasonable opinion of the Authority and subject to prior discussion with the Contractor these payments are still required.
- 4.3A The Authority reserves the right to recover from the Contractor any sum of money allocated in a specific financial year but not actually spent by the financial year ending 31st March. Where reasonably possible such recovery will be by way of set off against future payments. In the event of the Authority exercising its right under this Clause 4.3A, a new payment schedule will be issued with the Approved Cost adjusted accordingly.
- 4.4. The total amount to be paid by the Authority to the Contractor in any financial year shall not exceed the relevant amount detailed in Section 4 unless the Authority instructs the Authority's Representative to apply a compounded annual inflationary uplift. The Authority shall apply uplifts only after obtaining approval from finance and HM Treasury. For illustration if the inflationary uplift in year 2 is set at 3% and year 3 at 1%, year 2 fees would be increased by 1.03 and year 3 by $1.03 \times 1.01 = 1.0403$. Where there is an upper limit to programme funding the limit will be applied excluding inflation. Such adjustment shall not require a Variation. Subject to these limits the Contractor may administer the funds paid in accordance with Section 4 within the terms of this Contract and in connection with the Research without further reference to the Authority.
- 4.5. The Contractor is responsible for any payments to third parties and shall ensure that such payments are made promptly. The Authority is not obliged to make any payments to any third party and the Contractor shall indemnify the Authority against any loss, damage, cost or expense incurred by the Authority as a result of any claim made or intimated against the Authority as a result of the Contractor's failure to pay any third party promptly or at all.
- 4.6. Where any payment to the Contractor by the Authority under this Contract will flow through to a third party, the Contractor shall ensure that, before any funds are released to the third party:
 - 4.6.1. The Contractor has completed appropriate checks on the proposed recipient and is satisfied that the proposed recipient has adequate measures in place to prevent Fraud, bribery or corruption;
 - 4.6.2. The Contractor is entitled to receive detailed reports and to conduct reasonable audits and other checks on the proposed recipient taking into account the value of the funds to be released so that the Contractor can fulfil its obligations under Clause 13.
- 4.7. The Authority may request from the Contractor at any time such evidence as may

reasonably be required to show that the Contractor has used the amounts paid in accordance with Section 4 within the terms of this Contract and in connection with the Research. The Contractor shall maintain proper financial records relating to the Research at all times during the Research Period and for a period of six (6) years after the end of the Research Period.

- 4.8. The Contractor grants to the Authority and to any statutory or regulatory auditors of the Authority and to its or their authorised agents the right of reasonable access to (and if necessary to copy) the relevant financial records and/or other information relating to the financial records during normal business hours which shall mean 9am - 5pm Monday to Friday excluding Bank Holidays as specified by The Bank of England for the duration of the Research Period and for a period of six (6) years after the end of the Research Period.
- 4.9. The Contractor shall provide all reasonable cooperation and assistance at all times during the currency of this Contract and for a period of six (6) years after termination or expiry of this Contract for the purposes of allowing the Authority to obtain such information as is necessary to fulfil the Authority's obligations to supply information for Parliamentary, Governmental, Judicial or other regulatory or administrative purposes and/or to carry out an audit of the Contractor's compliance with this Contract including all activities, performance, security, ODA compliance within the UK and abroad, and integrity in connection therewith. The costs of any such audit or the provision of any such cooperation, assistance or information shall be borne by the Contractor.
- 4.10. The Authority shall confirm to the Contractor in writing, within thirty (30) calendar days of receipt by the Authority of the Reporting Milestone either that:
 - 4.10.1. the Reporting Milestone has been achieved by the Reporting Milestone Date to the reasonable satisfaction of the Authority, in which case, the Authority shall make the next payment due to the Contractor in the Payment Schedule; or
 - 4.10.2. the Reporting Milestone has not been achieved to the reasonable satisfaction of the Authority by the relevant Reporting Milestone Date and that the next payment due to the Contractor in the Payment Schedule shall not take place, in which case the Authority shall provide the Contractor with reasonable details of the grounds on which they have reached this decision.
- 4.11. The Authority may, at its sole discretion, grant the Contractor a reasonable period of time ("**Reporting Milestone Extension**"), in order to address the reasons why the Authority has judged that a particular Reporting Milestone has not been met. Upon the expiry of a Reporting Milestone Extension, the Authority shall, at its sole discretion, decide whether or not to permit full or partial payment of the relevant payment in the Payment Schedule of funding to the Contractor. A failure by the Contractor to meet a Reporting Milestone Date (or Reporting Milestone Extension) without valid reason shall constitute a material breach of this Contract.
- 4.12. On completion of the Research Period, the final payment in respect of costs properly incurred under this Contract will be paid by the Authority to the Contractor within thirty (30) calendar days of all of the following objectives being satisfied:
 - 4.12.1. the Research has been completed to the reasonable satisfaction of the Authority;

- 4.12.2. the reports required under Clauses 13 and 14 have been submitted by the Contractor to the Authority, and the Authority shall not unreasonably withhold or delay approval;
 - 4.12.3. agreement has been reached in respect of any items remaining for disposal.
- 4.13. If at any time an overpayment has been made to the Contractor for any reason whatsoever, the amount of such overpayment shall be taken into account in assessing any further payments, or shall be recoverable from the Contractor at the Authority's discretion.
- 4.14. The Authority shall be under no obligation to make any payment on claims received more than twelve (12) months after the completion of the Contract Period and there will be a general presumption against paying claims received after this date, unless an extension has been requested and agreed in writing.

5. SET OFF

- 5.1. If any sum of money shall be due from the Contractor to the Authority or any other Government department office or agency of the Crown, the same may be deducted from any sum then due or which at any time thereafter may become due to the Contractor under this Contract or under any other agreement with the Authority or with any other department, office or agency of the Crown. Such deduction shall not be made unless the Contractor has been notified in writing in advance by the Authority.

6. VARIATION

- 6.1. If at any time it appears likely that it will be appropriate to vary any material provision of the Contract, including, but not limited to:
- 6.1.1. a change of the Chief Investigator;
 - 6.1.2. discontinuation of an activity set out in Section 3 (Research); and
 - 6.1.3. the establishment of a new activity,

the Contractor shall inform the Authority in writing requesting a Variation to the Contract, giving full details of the justification for the request and giving proposals for the Variation to the Contract.

- 6.2. Upon receipt of a request under Clause 6.1, the Authority may:
- 6.2.1. agree to vary the Contract in a form provided by the Authority and signed by both Parties;
 - 6.2.2. vary the Research in a manner which the Contractor agrees can be carried out within the Research Period and Approved Cost;
 - 6.2.3. refuse the request and require the continuation of the Research in accordance with the Contract; or
 - 6.2.4. give notice of termination in accordance with Clause 20.3.
- 6.3. If any request made under Clause 6.1 is agreed by the Authority, the appropriate revision to the Contract shall not be valid or effective unless and until it has been recorded in a Variation to Contract Form as set out at Schedule E to Section 2 and signed by the duly authorized representatives of both Parties.
- 6.4. If at any time it appears likely that it will be appropriate to vary any provision of the Contract that does not fall within Clause 6.1, the Authority may agree to vary the

Contract by way of a letter agreement that shall not be valid or effective unless and until it has been signed by the duly authorized representatives of both Parties.

7. STAFF APPOINTMENTS

- 7.1. The Contractor agrees to use sufficient appropriately skilled resources to enable it to comply with its obligations under this Contract.
- 7.2. All staff providing services in connection with this Contract shall be bound by the same terms and conditions of service which are normally applicable to the Contractor's employees or the relevant employing Collaborator. Subject to the compatibility with this Contract, the Contractor shall take into account, as far as possible, the recommendations from Universities UK and the University and College Union on Codes of Practice for the employment of research staff on fixed term contracts.
- 7.3. The Authority has a commitment to equal opportunities to which the Contractor must adhere. The Contractor must not discriminate on the grounds of gender, race, disability, sexuality, age or religion. The criteria for short listing and appointment to posts funded by the Authority must be based solely on the knowledge, skills, experience and personal qualities which in the view of management are required for the successful discharging of the responsibilities of the post. All posts should be open to part-timers and job-share arrangements unless otherwise stated in the advertisement.
- 7.4. The Contractor will ensure that the terms and conditions of staff employed to provide services in connection with this Contract contain provisions in respect of intellectual property compatible with the terms of this Contract and in particular allow those staff to where reasonable and practicable publish the outcome of the Research in appropriate research journals.
- 7.5. Subject to Clause 9, the Contractor shall cause to be kept full, detailed and accurate records of all of activities and results obtained in connection with the Research. In this respect, the Contractor shall, and shall procure that the Contractor's staff, any Collaborators and Sub-contractors and their respective staff shall at all times:
 - 7.5.1. observe professional standards; and
 - 7.5.2. where relevant keep scientific notebooks recording all research, development and other work carried out in respect of the Research 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.
- 7.6. The Contractor shall upon request make available to the Authority copies of all records generated in connection with the Research, including for the avoidance of doubt, records generated by employees of the Contractor, or any employees of the Collaborator(s) or other Sub-contractors under Clause 7.5 and by any third parties working on the Research.

8. PUBLICITY, PUBLICATION, AND BRANDING

- 8.1. Before and after the start of the Research Period, and prior to any publication of the Research, Foreground IP, Research Data or of matters arising from the

Research or Research Data in accordance with Clauses 3.1 and this Clause 8, the Contractor shall not without the prior written consent of the Authority, which shall not be unreasonably withheld or delayed, release, or otherwise make available to third parties, any information relating to this Contract or the Research by means of any public statement, in particular any media announcement or display or by putting on any website or oral presentation to meetings where the results are likely to be reported by the media. This Clause shall not apply where the Contractor has a contractual, legal or similar obligation to publish specific details about the Contract or the Research.

- 8.2. The Contractor must notify the Authority's Representative of any intention to issue a press release (whether it will be issued by the Contractor or any other party) at least fourteen (14) calendar days prior to any press release issued by it or on its behalf, directly related to the Research or Foreground IP, Arising Know How or Research Data or of matters arising from such Research. The Contractor shall send one draft copy of the proposed press release to the Authority's Representative at least fourteen (14) calendar days before the date intended for release. For the avoidance of doubt this obligation shall continue in full force and effect following expiry of the Research Period.
- 8.3. In the event that the Contractor fails to comply with Clause 8.1 or 8.2, the Authority reserves the right to:
 - 8.3.1 deem this to be a material breach and terminate this Contract in accordance with Clause 20.3 herein; and/or
 - 8.3.2 suspend or reduce its payment of amounts due under the payment schedule in Section 4 of the Contract; and/or
 - 8.3.3 require repayment of all or part of the funding provided under this Contract.

The Contractor further acknowledges that a breach of Clause 8.1 [or Clause 8.2] by the Contractor may be taken into account by the Authority when considering future applications for NIHR funding from the Contractor.

- 8.4. The Contractor shall comply with guidance and advice from the Authority on branding and publicity which may be issued from time to time including, but not limited to, permitted use of the NIHR and Department of Health and Social Care brands, names and logos and ensuring all branding references to the Global Health Research Groups are prefixed with the term "NIHR".
- 8.5. Notwithstanding the provisions of Clause 16, the Authority's Representative may at any time publish the Reports for any non-commercial purpose or in accordance with the aims and terms of the Authority's statement on Open Access to research "Statement on DH/NIHR-funded research and UK PubMed Central". Such non-commercial 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 Authority's behalf by the Authority's Representative. The timing of any such publication will be subject to consultation with the Contractor 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.
- 8.6. The Contractor shall assign to the Authority on behalf of the Crown all Intellectual Property rights in the Report to which the Contractor is legally entitled, by signing a document in the form shown at the Schedule A to this Section 2 and returning it to the Authority on signature of this Contract. For the avoidance of doubt this

assignment relates to the copyright in the Report and does not extend to the Intellectual Property described therein.

8.7 The Contractor undertakes to obtain an assignment to the Authority of any Intellectual Property rights in the Report where such rights are the property of a person or organisation other than the Contractor. The Contractor shall provide the Authority with all appropriate details, including proof that the Contractor has obtained such an assignment and details of the acknowledgements required by owners of the rights assigned.

8.8 The Authority will ensure that any Queen's Printer and Controller of HMSO copyright publication arising from the Report carries the following statement:

"© Queen's Printer and Controller of HMSO 20xx [insert year of publication].

This work was produced by (name of author/organisation) under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care".

8.9 The Contractor shall ensure that any outcome of the Research or details of the progress of the Research are prepared and submitted for publication in a suitable peer-reviewed journal in accordance with this Clause 8 as soon as is appropriate and in any event no later than one year after the conclusion of the Research.

8.10 The Contractor shall ensure that any publication of or resulting from research carried out under this Contract shall acknowledge, in any acknowledgement section, the Authority's financial support and carry a disclaimer as the Authority may require or in the absence of direction from the Authority a notice as follows:

"This research was commissioned by the National Institute for Health Research using Official Development Assistance (ODA) funding. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care."

9 **CONFIDENTIALITY**

9.1 In respect of any Confidential Information it may receive from the other Party and subject always to the remainder of this Clause 9, the receiving party undertakes: to keep such Confidential Information secret and strictly confidential; and, not disclose any such Confidential Information to any third party (other than those involved in the Research who are bound by similar confidentiality obligations) without the disclosing Party's prior written consent; and, not to make any use of the Confidential Information save to the limited extent necessary for the performance of the Research, provided in each case that:

9.1.1 the receiving party shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the commencement of this Contract; and

9.1.2 nothing herein shall prevent either party from using data processing techniques, ideas, Know How and the like gained during the performance of this Contract in the furtherance of its normal business, to the extent that this use: is consistent with Clause 16.2; and, does not result in a disclosure of any Confidential Information or infringement of any valid Intellectual Property of either Party or the unauthorised processing of any Personal Data.

- 9.2 Clause 9.1 shall not apply to any Confidential Information received by one Party from the other:
- 9.2.1 which is or becomes public knowledge (otherwise than by breach of this Clause 9);
 - 9.2.2 which was in the possession of the receiving party, without restriction as to its disclosure, before receiving it from the disclosing party;
 - 9.2.3 which is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure;
 - 9.2.4 where the disclosing Party has authorised the disclosure of the Confidential Information;
 - 9.2.5 which is independently developed by the receiving party without access to the Confidential Information; or
 - 9.2.6 which must be disclosed pursuant to a statutory, legal or parliamentary obligation placed upon the Party making the disclosure, including any requirements for disclosure under the FOIA or the Environmental Information Regulations pursuant to Clause 34 (Freedom of Information).
- 9.3 The obligations of each of the Parties contained in Clause 9.1 above shall continue without limit of time.
- 9.4 In the event that the Contractor fails to comply with Clause 9, the Authority may, without prejudice to any other rights or remedies available to the Authority, terminate this Contract with immediate effect by giving notice in writing to the Contractor.

10 DATA PROTECTION

- 10.1 In relation to the performance of this Contract and the Research and/or as required for the proper and lawful operation of this Contract and the Research, the Contractor will, and is responsible for ensuring that each Collaborator will comply with the directly applicable requirements and obligations of the Data Protection Legislation.
- 10.2 The Contractor shall ensure that any Personal Data shall be treated as confidential at all times including during collection, handling and use, and that the Personal Data (including in any electronic format) shall be stored securely at all times and with all technical and organisational security measures that would be necessary for compliance with data protection legislation. The Contractor shall take appropriate measures to ensure the security of all Personal Data and guard against unauthorised access thereto or disclosure thereof or loss or destruction while in its custody.
- 10.3 The Contractor shall defend, fully indemnify and keep indemnified and shall hold harmless the Authority, its officers, employees and agents from and against any and all liabilities, losses, costs, charges and expenses incurred (either directly or, notwithstanding clause 24.5, indirectly) as a result of any claims, demands, actions and proceedings made or brought against the Authority by any third party in respect of any loss or distress suffered by the loss or unauthorised disclosure of Personal Data or medical records by the Contractor, or any of its Collaborators, sub-contractors, employees, agents or person within its control.
- 10.4 The Contractor shall at its own expense conduct any litigation arising from any claims, demands, actions or proceedings by any third party in respect of the loss

or unauthorised disclosure of Personal Data or medical records by the Contractor or any of its Collaborators, sub-contractors, servants, agents or persons within its control and all the negotiations for the settlement of the same and the Authority hereby agrees to grant the Contractor exclusive control of any such litigation or the negotiations for the settlement of the same.

10.5 The Contractor shall ensure that medical information relating to the individuals who are the subjects of the Research shall be used in accordance with:

10.5.1 the Medical Research Council's "Personal Information in Medical Research", as amended from time to time; and

10.5.2 the NHS Digital "Code of practice on confidential information", as amended from time to time.

10.6 No information which would lead to the identification of an individual shall be included in any publications without the prior agreement in writing of the individual concerned. No mention shall be made of individual officers of the Authority, nor shall information be included which might lead to their identification, without the prior agreement in writing of the Authority.

10.7 The Authority reserves the right upon giving reasonable notice and within normal working hours to request the Contractor to provide reasonable evidence in order to enable it to ascertain compliance with the Data Protection Legislation and the terms of this Clause 10.

10.8 The Contractor shall, from time to time, comply with any reasonable request made by the Authority to ensure compliance with this clause 10 or any minimum standard required by the Authority and with the Data Protection Legislation or other directly applicable data protection and/or privacy laws.

10.9 The Contractor shall not, by any statement, act or omission, cause the Authority to be in breach of or to incur any civil, criminal or other liability under any other law or regulation relating to data protection or privacy.

11 RIGHTS TO RESEARCH DATA

11.1 Subject to the provisions of Clauses 9, 10 and 11.4, and in the event that in the Authority's reasonable opinion the Research Data is not being appropriately managed, disseminated or used, the Authority reserves the right to have access to and to use the Research Data compiled during the course of the Research, and will respect existing confidentiality obligations in respect of any Research Data which it obtains, and to permit any Health Service Body to access and use the Research Data in order to: (i) support the development, promotion or provision of Health Care; or (ii) for any other purpose that is not a Commercial Use.

11.2 The Contractor shall not, and shall procure that each Collaborator shall not, enter into any agreement with any third party that:

11.2.1 limits or restricts the use of Research Data held by the Contractor and/or Collaborator; and/or

11.2.2 grants any form of exclusivity to a third party.

provided that the Authority recognizes that a third party that has supported the generation of Research Data may have a legitimate interest in limited exclusivity and therefore the Authority acknowledges that nothing in this clause 11.2 is intended to prevent the provision of Research Data directly related to Background IP provided by a third party to that third party on an exclusive basis

for a reasonable period of no longer than 18 months and subject always to clause 17.6.

- 11.3 The Contractor shall, at the request of the Authority, deposit both qualitative and quantitative Research Data in a relevant data archive subject to any reasonable delay necessary to enable the protection or exploitation of Foreground IP.
- 11.4 The Authority shall not be entitled to inspect, take or be supplied with copies of the Research Data other than in an anonymised form.
- 11.5 The Contractor shall ensure that all Research Data is anonymised and that the key to personal identities of all persons to whom the Research Data relates is kept in a separate and secure place. As a minimum, the Contractor shall ensure that such anonymisation satisfies the appropriate standard recommended by the Information Commissioner's Office from time to time.
- 11.6 In order to reflect the Authority's position on open access to research materials, where research materials recording the outcome of the Research or details of the progress of the Research are submitted for publication, the Contractor shall either:
 - 11.6.1 subject to confidentiality requirements and to applicable data protection considerations, make all information and data (including but not limited to Research Data) on which the research materials are based available on an open access basis; or
 - 11.6.2 include a statement with the research materials detailing how such information and data can be accessed.

12 RESEARCH PRACTICE AND ETHICS

- 12.1 The Contractor will ensure that the Research and any other research directly connected to the Research is conducted in accordance with:
 - 12.1.1 The Health Research Authority guidance "UK Policy Framework For Health and Social Care Research" or any guidance replacing it;
 - 12.1.2 "The Concordat to support Research Integrity";
 - 12.1.3 If relevant, the Health Research Authority guidance "Governance Arrangements for Research Ethics Committees ("GAfREC"); and/or
 - 12.1.4 Such other relevant guidance as may be issued from time to time by the Authority or the Health Research Authority and made available to the Contractor.
- 12.2 The Contractor shall use (and shall procure that each Collaborator shall use) all reasonable endeavours to comply with guidance and advice from the Authority on research governance and the use and implementation of NIHR model research agreements or those issued by Health Research Authority where possible, which may be issued from time to time.
- 12.3 The Contractor shall comply with all relevant legislation including but not limited to:
 - 12.3.1 The Medicines for Human Use (Clinical Trials) Regulations (SI2004/1031) as Amended;
 - 12.3.2 The Human Tissue Act 2004; and
 - 12.3.3 The Mental Capacity Act 2005.

- 12.4 Where any part of the Research is performed overseas, the Contractor shall ensure that:
- 12.4.1 Any Collaborators comply with, and, that part of the Research is conducted in compliance with, all relevant local legislation; and
 - 12.4.2 In any event, any part of the Research that is performed overseas is conducted to a standard equivalent to that required under the UK regulatory regime.
- 12.5 The Contractor will submit for review by a Research Ethics Committee recognised by the Authority any aspect of the Research where applicable and in accordance with Authority's prevailing guidance with a view to obtaining the approval of the necessary appropriate Research Ethics Committee (or equivalent) in respect of the Research. The Contractor shall inform the Authority's Representative when such approval has been given (whether unconditionally or subject to conditions) or withheld.
- 12.6 The Contractor shall ensure that any part of the Research requiring the approval of a Research Ethics Committee shall not commence until such approval is given.
- 12.7 The Contractor shall not use or permit any funding provided under this Contract to be used to support Research performed using animals.

13 MONITORING AND REPORTING

- 13.1 Progress of the Research will be reviewed periodically by the Authority's Representative against the specifications detailed in Section 6.
- 13.2 The Contractor shall provide written reports on the progress of the Research in accordance with Section 6. These reports shall include financial details and shall be in a form and otherwise in compliance with the format set out by the Authority's Representative as amended from time to time.
- 13.3 During the Research Period the Contractor shall provide verbal or written reports as reasonably required by the Authority or the Authority's Representative on any aspect of the Research.
- 13.4 During the Research Period and for up to five (5) years after the Completion Date, at the request of the Authority the Contractor shall provide written case studies in a form set out by the Authority's Representative on any aspect of the Research where appropriate.
- 13.5 The Contractor shall provide any reports requested by the Authority pursuant to Clause 13.3 or 13.4 in accordance with any reasonable dates or durations specified by the Authority.

14 FINAL REPORT AND RESEARCH OUTPUTS INFORMATION

- 14.1 The Contractor shall provide a draft final report on the Research within fourteen (14) calendar days of the Completion Date or date of termination howsoever terminated. The draft final report shall be in a form to be agreed with the Authority or as otherwise required by the Authority's Representative and shall include an outline of the Research Data, methods, an outline of any Foreground IP, Arising Know How and the final conclusions of the Research together with management information and any other information relating to the Research up to the Completion Date.
- 14.2 The Contractor shall also provide, in a form to be agreed with the Authority, a draft summary final report of the findings for the Research.

14.3 If within one (1) year of the end of the Research Period the Contractor has not produced a report which satisfies the Authority, the Authority may, at the cost and expense of the Contractor, prepare and publish, or arrange for the preparation and publication of, such a report.

14.4 For the duration of the Research Period and for a period of up to five (5) years after completion of the Research the Contractor will comply with requests for survey information collected through NIHR-authorized web-based systems.

15 **SITE VISIT GROUP**

15.1 In addition to informal visits made by the Authority's Programme Management Representative, the Authority may appoint a Site Visit Group, made up of a small team of independent experts, and observers of the Authority and NIHR. The Contractor 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 Research is being conducted in the UK and/or at the Collaborator(s) in the relevant DAC list country or countries (see References for DAC List of ODA Recipients) to consult informally with the staff working on the Research, to evaluate progress, performance and key issues and have access to any scientific, technical, operational, financial or legal information relevant to this Contract and to report back to the Authority on its findings. The Site Visit Group shall be subject to the same confidentiality obligations as specified in this Contract.

15.2 The Contractor shall be given one (1) month's written notice prior to any visit by the Site Visit Group.

15.3 The Site Visit Group may recommend that the Authority terminate the Research or an element of the Research where it has identified a serious failure in the progress, management or conduct of the Research (including a finding that the Research will be unable to achieve the next milestone within a reasonable time period). The Site Visit Group may also alert the Authority to any external scientific, technical or commercial barrier which means that the Research is unlikely to succeed in its objectives. If the Site Visit Group makes such a recommendation pursuant to this Clause 15.3 the Authority may, after hearing representation from the Contractor, take action at its discretion and acting reasonably which may include variation or termination of the Contract or an element of the Research pursuant to Clause 20.3.

15.4 The Authority may, at its sole discretion, and acting reasonably, allow the Contractor 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). Where the Authority grants the Contractor a period of time to correct such failings and the Contractor does not correct such failings within the period specified by the Authority (if any), the Authority shall retain the right to terminate this Contract pursuant to Clause 20.3.

15.5 The Contractor will co-operate fully with the Site Visit Group prior to and during visits.

16 **INTELLECTUAL PROPERTY RIGHTS**

16.1 In accordance with Section 6, the Contractor will prepare and submit to the Authority for approval a draft policy recording a set of working principles relating to the ownership, management and use of Intellectual Property ("**IP Policy**"). As a minimum, the IP Policy will give guidance relating to the management of Foreground IP, Arising Know How and Research Data including the identification,

protection, prosecution, maintenance, dissemination and exploitation of IP rights. The Authority is entitled to review and comment on the draft policy when received and the Contractor will make reasonable revisions in order to accommodate the Authority's comments. Once the Authority has approved the draft policy, the Contractor will implement it (including in accordance with Clause 3.11) and maintain it in force for the duration of the Research Period.

16.2 In accordance with Clauses 3.11 to 3.13 or as agreed with the Authority, the Contractor shall put in place with each Collaborator a Collaboration Agreement consistent with Schedule D and the IP Policy to ensure that:

16.2.1 Each Collaborator is obliged to perform the Research in accordance with this Contract and either: (i) to assign all Foreground IP and Research Data to the Contractor; or (ii) where Foreground IP or Research Data vests in the Collaborator(s), each Collaborator irrevocably agrees in writing that:

16.2.1.1 any Foreground IP and/or Research Data it retains will be subject to and be managed by that Collaborator in accordance with the provisions of this Contract as if such Collaborator were a party to this Contract; and

16.2.1.2 relevant rights, licences and obligations as are recorded in the Contract will be directly enforceable against the appropriate Collaborator(s) by the Authority pursuant to The Contracts (Rights of Third Parties) Act 1999 or other suitable mechanism.

16.2.2 Arising Know How may be used by the Contractor on a world-wide, royalty free, non-exclusive, transferable and sub-licensable basis in the course of the Contractor's normal activities or to achieve Patient Benefit. However:

16.2.2.1 the Contractor may not, and shall ensure that the Collaborator(s) may not, use, or permit any other party to use, the Arising Know How for any Commercial Use without the prior written consent of the Authority obtained in accordance with Clause 17.6;

16.2.2.2 the Contractor and Collaborator(s) may only use the Arising Know How in accordance with Clause 9.1.2;

16.2.3 Each Collaborator will, upon reasonable request, make available their employees and/or consultants for discussion with the Site Visit Group as referred to in Clause 15;

16.2.4 Each Collaborator shall be under obligations of confidence concerning the Foreground IP and Research Data on terms equivalent to those set out under this Contract; and

16.2.5 Each Collaborator shall keep detailed records including, where relevant, scientific notebooks of all of its activities and upon request shall make available copies to the Authority.

16.3 Foreground IP, Arising Know How and Research Data which may arise as part of, incidental to or resulting from the Research shall either: (i) vest in the Contractor; or, (ii) where a Collaboration Agreement is in place and has been approved by the Authority vest in the relevant Collaborator or be owned and managed in accordance with Schedule D and the Collaboration Agreement.

16.4 The Contractor shall use reasonable efforts to make available, and, subject to Clause 16.2, ensure that each Collaborator shall make available, the Background IP or Know-How that is owned or controlled by the Contractor or the Collaborator(s) and that is necessary or useful for undertaking the Research and for the protection, dissemination or exploitation of the Foreground IP. Where the Contractor and subject to Clause 16.2, the Collaborator have responsibility for filing, prosecuting, maintaining, defending and enforcing protection for such Background IP, the Contractor or, subject to Clause 16.2, the Collaborator, shall retain this responsibility unless otherwise agreed in writing and in any event at no cost to the Authority. If the Contractor, or subject to Clause 16.2, the Collaborator wishes to cease doing so in relation to any of such Background IP, it shall notify the Authority as soon as reasonably practical and in any event no less than two (2) months prior to discontinuing its maintenance, defence or enforcement of such Background IP and the Authority shall have the right but not the obligation to take over responsibility for such Background IP. To the extent that it is legally able to do so, the Contractor or Collaborator shall licence or assign the Background IP to a nominee of the Authority's choosing on fair and reasonable terms taking account of the permitted use of such Background IP.

16.5 The Contractor shall grant (and shall procure that the Collaborators grant) to the Authority a non-exclusive, irrevocable, royalty-free, worldwide licence together with the right to grant sub-licences to Health Service Bodies or others directly engaged in providing Health Care, permitting the Authority to:

16.5.1 use and publish (in accordance with Clauses 8 and 9):

- 16.5.1.1 any information relating to the Research which is not Confidential Information of the Contractor;
- 16.5.1.2 any Foreground IP;
- 16.5.1.3 Research Data;
- 16.5.1.4 Reports;
- 16.5.1.5 Arising Know How; and,
- 16.5.1.6 conclusions arising from the Research

and in each case, the Authority intends to exercise this right only where the Authority's reasonable opinion the Contractor or Collaborator (as appropriate) is not appropriately managing, disseminating or using such items and in each case the Authority is permitted to use or make available such items as it sees fit in support of the development, promotion or provision of Health Care or for any other purpose that is not a Commercial Use; and

16.5.2 use the Contractor's Background IP and Collaborator Background IP but solely to the extent that it is necessary in order to exercise the licence granted in Clause 16.5.1.

In each case, where any third party has rights existing at the date of the licence granted in this Clause such licence will be subject to those third party rights and the Contractor shall: (i) notify the Authority of such rights; and (ii) make reasonable efforts to overcome or to negotiate exclusions from such rights for the benefit of the Authority.

16.6 The Contractor shall:

- 16.6.1 ensure that for any part of the Research involving a third party, it shall have in place suitable agreements, including, for example, a drug supply agreement or software supply agreement, (“**Research Project Agreements**”) to ensure effective performance of the Research, ownership and/or management of Foreground IP, Arising Know How and Research Data, access to Background IP and reporting obligations in order to enable the Contractor to successfully deliver the Research and ensure the effective exploitation of and maximise the use of any Foreground IP, Arising Know How and Research Data; and
- 16.6.2 ensure that access to Background IP shall be on fair and reasonable terms at no charge where access to the Background IP is necessary for the delivery of the Research or on fair and reasonable commercial terms where access to the Background IP is necessary for the exploitation of Foreground IP, Arising Know How and Research Data.
- 16.7 Where the Contractor and Collaborator(s) can reasonably expect to do so they shall enter into agreements in which the Intellectual Property arrangements do not adversely affect or restrict the Contractor’s ability to comply with the terms of this Contract.

17 **EXPLOITATION OF INTELLECTUAL PROPERTY**

- 17.1 The Contractor shall inform the Authority in a timely manner and in any event before making any Commercial Use of, or accepting any proposal to make Commercial Use of, the Foreground IP, Arising Know How or Research Data.
- 17.2 The Contractor shall procure that any party (including but not limited to the Collaborators, Sub-contractors or any other party involved in the Research) performing the Research develops, implements and maintains procedures consistent with Schedule D and the IP Policy for the management of Intellectual Property and in particular, but without limitation, shall ensure that:
- 17.2.1 the Foreground IP is identified and recorded;
- 17.2.2 prior to any publication, any patentable or registrable elements of the Foreground IP are identified, duly considered for patentability or other registration and, where it is commercially reasonable to do so and is an appropriate means of achieving Patient Benefit, patent applications or other registrations are filed in respect thereof at patent offices in territories where products or services arising from the Foreground IP may be made, sold or used in accordance with the Contractor IP Policy;
- 17.2.3 the Authority is notified within six (6) months of receipt of disclosure of Foreground IP that may be protected by any form of registration and in the event that the Contractor or, subject to Clause 16.2, any Collaborator, decides not to protect the Foreground IP by applying to register the appropriate Foreground IP, the Contractor agrees to or, subject to Clause 16.2, shall ensure that the Collaborator, agrees to communicate this decision to the Authority and the Authority shall have the right but not the obligation to take assignment of the Intellectual Property associated with the disclosure free of charge and to manage the associated Intellectual Property, save that the Contractor or subject to Clause 16.2, the Collaborator, may reasonably request an extension of up to one (1) year from the date of any such notification under this Clause 17.2 to enable further validation or development of the Foreground IP prior to protection;

- 17.2.4 in exercising the rights in Clause 17.2 the Contractor takes due consideration of the Authority's attitude to the inappropriate use of patents which it considers detrimental to scientific endeavour or to advances in healthcare. The Authority believes that the basic DNA sequence of humans and other organisms should be placed in the public domain as soon as is practical, without any fees, patents, licences or limitations on use, giving free and equal access to all;
- 17.2.5 all such applications for registration are diligently prosecuted having regard to all relevant circumstances; and
- 17.2.6 in the event that the Contractor or, subject to Clause 16.2, a Collaborator(s), elects to abandon prosecution of an application for registration of Intellectual Property protecting applications of the outcome of the Research, the Contractor shall inform the Authority's Representative as soon as reasonably practical and in any event no less than two (2) months in advance of the patent application lapsing and the Authority shall have the right but not the obligation to take assignment of the Intellectual Property associated with the application free of charge and to manage its prosecution.
- 17.3 The Contractor shall, and shall procure through a Collaboration Agreement that each Collaborator shall, permit the Authority to monitor the operation and effectiveness of the Contractor's and Collaborator's procedures for the management of Intellectual Property in such ways as the Authority considers reasonably necessary to ensure that any Foreground IP, Arising Know How or Research Data generated is disseminated and/or exploited for the public benefit and to maximise Patient Benefit. This right shall include but not be limited to the right of the Authority (or its authorised representative) to inspect and audit the Contractor's and/or the Collaborator's records kept pursuant to Clause 17.4.3, subject to the Authority providing ten (10) Business Days' written notice to the Contractor. This right of inspection and audit may be performed once in each twelve (12) month period following the Commencement Date.
- 17.4 Consistent with the good management of Intellectual Property and the terms of the Contractor IP Policy, the Contractor and subject to Clause 16.2, each Collaborator shall:
- 17.4.1 where reasonable and practicable, promote the dissemination of the Foreground IP, Arising Know How and Research Data in order to achieve Patient Benefit;
- 17.4.2 where reasonable and practicable and subject to obtaining the prior written consent of the Authority, exploit such Foreground IP, Arising Know How and Research Data in order to generate either capital or revenue or both; and
- 17.4.3 pursuant to Clause 7.5 keep proper records showing the description of the Background IP used and Foreground IP generated.
- 17.5 The Contractor and each Collaborator shall agree between themselves who shall take principal responsibility for the exploitation and/or commercialisation of each part of Foreground IP (and the associated Background IP), Arising Know How and Research Data and shall inform the Authority accordingly.
- 17.6 The Contractor shall, and shall ensure that each Collaborator shall obtain the written consent of the Authority prior to making any Commercial Use, or permitting

any third party to make any Commercial Use, of the Foreground IP or Arising Know How or Research Data. Any request for consent must be submitted to the Authority in writing and be accompanied by sufficient information (including reasonable details of the proposed Commercial Use and any parties involved in the proposed Commercial Use) to allow the Authority to consider the request. The Authority will within thirty (30) days of receipt of a written request for consent inform the Contractor or Collaborator if the Authority requires the Contractor or Collaborator to enter into a commercialisation agreement with the Authority as a condition of granting such consent. Any such commercialisation agreement shall, as a minimum:

- 17.6.1 address the distribution of revenue, equity or other benefits arising from the proposed commercialisation arrangements and rights to use the Foreground IP, Arising Know How or Research Data;
 - 17.6.2 reflect the Authority's policy from time to time relating to the allocation and use of revenue, equity or other benefits arising from the proposed commercialisation arrangements and rights to use the Foreground IP, Arising Know How or Research Data;
 - 17.6.3 take into consideration the relative contribution of the Authority, the Contractor, each Collaborator and other third party funders or contributors to the Foreground IP, the Arising Know How or the Research Data.
- 17.7 Unless agreed otherwise in writing, the Contractor shall ensure that any proceeds of commercialisation allocated to the Authority as a result of any Commercial Use are:
- 17.7.1 distributed according to the terms of the relevant revenue sharing agreement; or
 - 17.7.2 retained by the Contractor or Collaborator for use as directed by the Authority in support of further research.
- 17.8 In the event that the Contractor or pursuant to Clause 16.2, any Collaborator fails to comply with either of Clauses 17.6 or 17.7 the Authority reserves the right to deem this to be a material breach and terminate this Contract in accordance with Clause 20.3 herein.
- 17.9 In the event that the Contractor or any Collaborator notifies the Authority of intended commercialisation under Clause 17.6, then the Contractor or Collaborator should take due consideration of the Authority's attitude to access to essential health related technologies including medicines in the developing world. The Authority is mindful of the importance of the development and distribution of new health-related technologies for less developed countries. The Authority's policy on patenting is to prosecute patent applications in less developed countries only as necessary (for example, to provide development and marketing leverage for new products, or to exert leverage over global licensees). The Authority's policy on licensing is to grant licences with provisions that seek to increase the availability of medicines at affordable prices to less developed countries (examples include dividing up territories between a commercial and a not-for-profit partner, providing for developing world territories to revert to the institution if not exploited by the commercial partner or requirements for products to be supplied to the developing world at or close to cost).
- 17.10 If the Contractor or, subject to Clause 16.2, any Collaborator does not reasonably

protect, manage or exploit any Foreground IP arising out of the Research according to the terms of this Contract or if this Contract is terminated according to Clause 20.3, then the Authority shall have the right acting reasonably and subject to the prior rights of third party licensees or Collaborators, but not the obligation, to take assignment of and protect, manage and exploit such Foreground IP. Such right shall be exercised no earlier than six (6) months after the Authority has given the Contractor or Collaborator notice in writing that it is failing to protect, manage and exploit such Foreground IP to the Authority's satisfaction. However, the Authority may exercise such right sooner where it reasonably considers that the opportunity to protect, manage or exploit such Foreground IP for the public benefit could be lost if more immediate action is not taken. The Contractor agrees (and shall procure that each Collaborator agrees) to do, and will ensure that its employees, students and any third party acting on its behalf do, all acts required by the Authority to further such protection and exploitation including the delivery of all necessary written information including copies of any notebooks maintained throughout the Research.

- 17.11 If the Contractor wishes to use any third party (excluding its professional advisors) to carry out its obligations with respect to this Clause 17 other than any third party specified in the Collaboration Agreement then it must provide details of the proposed third party to the Authority and obtain the Authority's prior written approval to such third party carrying out exploitation activities with respect to the Foreground IP, Arising Know How or Research Data. Notwithstanding the foregoing, the Contractor will work in collaboration with each Collaborator to fulfil its obligations subject to the provisions of Clauses 16 and 17.
- 17.12 The Contractor should communicate with and keep informed the Authority's Representative, NIHR CCF and such other individuals as the Authority may notify to the Contractor from time to time in all matters relating to this Clause 17.
- 17.13 The Contractor shall do or procure to be done all such further acts and things and execute or procure the execution of all such other documents as the Authority may from time to time require for the purpose of giving the Authority the full benefit of the provisions of this Contract.
- 17.14 The Authority may, by notice in writing, require the Foreground IP, Arising Know How and/or Research Data to be promptly assigned to the Authority if the Contractor or a relevant Collaborator is subject to an Insolvency Event.

18 DUTY OF CARE

- 18.1 The Contractor owes a duty of care to all those employed or retained by the Contractor (including but not limited to Key Staff) to perform the Research and is responsible for the health, safety, security of life and property and general wellbeing of such persons and their property.
- 18.2 The Contractor warrants that it has and will throughout the duration of the Research Period:
- 18.2.1 carry out the appropriate risk assessment with regard to the performance of the Research;
 - 18.2.2 provide all those employed or retained by the Contractor (including but not limited to Key Staff) to perform the Research with adequate information, instruction, training and supervision;

- 18.2.3 have appropriate emergency procedures in place to ensure that the Research can be performed without damage to the health, safety, security of life and property and general wellbeing of all those employed or retained by the Contractor (including but not limited to Key Staff) to perform the Research.
- 18.3 The provision of information of any kind whatsoever by the Authority to the Contractor shall not in any respect relieve the Contractor from responsibility for its obligations under this Clause 18. The Contractor accepts that the positive evaluation of any part of the Contractor's proposal for the performance of the Research and the execution of this Agreement is not an endorsement by the Authority of any arrangements which the Contractor has made for the health, safety, security of life and property and wellbeing of all those employed or retained by the Contractor (including but not limited to Key Staff) to perform the Research.
- 18.4 The Contractor acknowledges that the Authority accepts no responsibility for the health, safety, security of life and property and general wellbeing of all those employed or retained by the Contractor (including but not limited to Key Staff) to perform the Research.
- 18.5 The Contractor shall ensure that training and insurance arrangements made to cover all those employed or retained by the Contractor (including but not limited to Key Staff) to perform the Research, are reasonable and prudent in all circumstances, including in respect of death, injury or disablement, and emergency medical expenses.
- 18.6 The costs of any insurance specifically taken out by the Contractor to support the performance of the Research may be included as part of the management costs of the Research, and must be separately identified in all financial reporting relating to the Research.

19. NIHR ACADEMY

- 19.1 The Contractor shall identify to the Authority all individual staff employed to provide services in connection with this Contract, to enable the Authority to maintain a record of the membership of NIHR Academy and the wider NIHR research workforce.
- 19.2 The Contractor shall inform the Authority immediately of any suspension or termination of employment of any staff providing services in connection with this Contract.
- 19.3 The Contractor shall make reasonable efforts to ensure that individuals employed to provide services in connection with this Contract:
- 19.3.1 abide by the rules, regulations and codes of conduct of their employer;
 - 19.3.2 abide by the rules, regulations and codes of conduct of their professional regulatory bodies where applicable;
 - 19.3.3 comply with relevant guidance published by the Authority on the conduct of research;
 - 19.3.4 are made aware of the NIHR's Privacy Policy available through the NIHR website; and

19.3.5 comply with guidance on membership of NIHR Academy as published from time-to-time on the NIHR website.

19.4 The Contractor shall use reasonable endeavours to comply with guidance and advice from the Authority on national training initiatives which may be published from time to time.

20. TERMINATION UPON OCCURRENCE OF EVENTS

20.1. Without prejudice to any other provision of this Contract, this Contract may be terminated by either Party giving three (3) months' notice in writing to the other. Should the option to terminate be exercised by the Authority under this Clause 20.1, it shall indemnify the Contractor from and against all and any actual loss unavoidably incurred by reason or in consequence of the termination provided that the Contractor takes all immediate and reasonable steps to minimise the loss.

20.2. The Authority will not pay any sum under Clause 20.1 which, when taken together with any sums paid or due or becoming due to the Contractor under this Contract, will exceed such total sums as would have been payable under this Contract if the Contractor had fulfilled its obligations under this Contract.

20.3. The Authority may at any time by notice in writing terminate this Contract without liability for any damage, loss or expenses arising as a result of or in connection with such termination if:

20.3.1.the Contractor is subject to an Insolvency Event;

20.3.2.the Contractor is in material breach of any of the terms and conditions of this Contract;

20.3.3.in the case of a breach capable of remedy, it fails to remedy that breach within thirty (30) calendar days (or any other period agreed in writing with the Authority) of the service of a written notice by the Authority specifying the breach and requiring its remedy; or

20.3.4.the breach is not capable of remedy; and where the Authority then makes other arrangements for the provision of the Research, the Authority is entitled to recover from the Contractor the direct cost of making those other arrangements; or

20.3.5.an event of Force Majeure, as defined in Clause 23 exists for more than six (6) months; or

20.3.6.any provision of this Contract (other than as previously specified in the preceding provisions of this Clause 20) expressly entitles the Authority to terminate this Contract; or

20.4 Not used

20.5 In addition, the Authority shall be entitled to terminate this Contract with immediate effect by notice in writing to the Contractor if the Site Visit Group recommends termination of the Research in accordance with Clause 15 and/or the Contractor fails to correct any identified failings within the time period granted by the Authority (if any) under Clause 15.3.

20.6 Termination of this Contract by the Authority under Clauses 2.2, 20.3 and 20.5 of this Clause 20 shall be: (i) with immediate effect; or, (ii) otherwise with effect from the expiry of such notice period as the Authority provides, in its discretion and which shall be a minimum of three (3) months and not exceeding six (6) months.

21. CONSEQUENCES OF TERMINATION

21.1. Termination of this Contract, however caused, shall not:

21.1.1. release the Contractor from any duty or obligation of confidence, in particular as imposed by Clauses 8 – 11 inclusive, which falls on it, or its Sub-contractors, agents, employees or former employees, under this Contract or under the general law governing confidential information; or

21.1.2. prejudice or affect any rights, action or remedy which shall have accrued before termination or shall accrue thereafter to any Party.

22. EQUIPMENT

22.1. The Contractor shall (and shall procure that each Collaborator shall) take all practical steps to purchase all materials and equipment identified in the Application at a fair and reasonable price. It is acknowledged that material and equipment must be purchased for the purposes of the Research only and that it may be purchased by and/or for the Contractor or relevant Collaborator based in the UK or low/middle income country. The Authority may inspect the original quotations and invoices issued to the Contractor or relevant Collaborator for equipment purchased in connection with the Research and recover any funds provided for the purchase if the Contractor does not provide this documentation on request.

22.2. At the end of the Research Period, and after the final presentation of the final report required under Clause 14 all equipment purchased for use on the Research with funds provided by the Authority shall:

22.2.1. continue to be used for ODA-eligible research for which it was originally purchased;

22.2.2. become the property of the Contractor or relevant Collaborator based in the UK or low/middle income country as appropriate.

23. FORCE MAJEURE

23.1. In the event that any Party is delayed in the performance of its obligations under this Contract by an event of Force Majeure, the obligations of the Parties under this Contract shall remain in suspense until the cause thereof has ceased. "**Force Majeure**" shall include any of the following: riots, sabotage, acts of war or piracy, destruction of essential equipment by fire, explosion, storm, flood or earthquake, and delay caused by failure of power supplied or transport facilities or any other cause beyond the control of the Parties which renders performance of this Contract impossible.

23.2. Neither of the Parties shall be liable to the other for any loss including but not limited to any damages or abatement of charges whether directly or indirectly caused or incurred by any failure or delay in the performance of its obligations due to Force Majeure.

23.3. If either of the Parties shall become aware of Force Majeure which give or are likely to give rise to any failure or delay on its part it shall forthwith notify the other by the most expeditious method then available and shall say how long it is estimated that such failure or delay shall continue.

23.4. Any failure by the Contractor to perform or any delay by either of the Parties in performing its obligations under the Contract which results from any failure or

delay in the performance of its obligations by any person, firm or company with which the Contractor shall have entered into any contract, supply arrangement or Sub-contract or otherwise, shall be regarded as a failure or delay due to Force Majeure only in the event that person firm or company shall itself be prevented from or delayed in complying with its obligations under such contract, supply arrangements or Sub-contract or otherwise as a result of Force Majeure.

- 23.5. The Authority and the Contractor may agree in writing and in advance that the Contractor shall not have the benefit of these Force Majeure provisions in respect of events that form the subject matter of the Research.

24. WARRANTIES AND LIABILITY

24.1. The Contractor warrants that:

- 24.1.1. it has the requisite capacity and authority and all necessary licences, permits and consents to enter into this Contract;
- 24.1.2. it has full capacity, power and authority and all necessary licences, permits and consents to assume and fully perform all of its obligations under this Contract;
- 24.1.3. it has, or has access to, sufficient resources to perform the Research as contemplated under this Contract and to meet its other obligations under this Contract;
- 24.1.4. there are no actions, suits or proceedings pending or, to the Contractor's knowledge, threatened against or affecting the Contractor before any court or administrative body or tribunal that might affect the ability of the Contractor to meet and carry out its obligations under this Contract;
- 24.1.5. it will be the legal and beneficial owner of all right, title and interest in and to the Foreground IP; or in the case of Foreground IP created by a Collaborator, it will enter into legally binding Collaboration Agreements with each Collaborator as required under this Contract.
- 24.1.6. in carrying out the Research, the Contractor will use all reasonable efforts to ensure that:
 - (a) sufficient authorisation has been obtained from any third party not a party to the Collaboration Agreement as set out in Schedule C to permit the use of any Intellectual Property owned or controlled by that third party that is reasonably necessary to enable the use of the Foreground IP, Arising Know How or Research Data to the extent necessary to exercise any rights under, or to perform, this Contract;
 - (b) the Research will be carried out by appropriately experienced, qualified and trained personnel with all due skill, care and diligence;
 - (c) the Contractor will, and will ensure that each Collaborator will, discharge their obligations under this Contract with all due skill, care and diligence including Good Industry Practice and (without limiting the generality of the foregoing) in accordance with its own established internal procedures; and
 - (d) funding will only be released by the Contractor to a proposed recipient after the Contractor has completed appropriate checks on the proposed recipient and is satisfied that the proposed recipient has adequate measures in place to prevent Fraud, bribery or corruption.

- 24.2. Except as expressly provided in this Contract, none of the Parties gives any warranties or makes any representations:
- 24.2.1. with respect to any of the Foreground IP and/or Contractor Background IP or any products derived from them, or their fitness for any purpose, or
 - 24.2.2. 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.
- 24.3. Notwithstanding any other provision of this Contract, each Party shall use its reasonable endeavours to mitigate losses it may incur that are covered by indemnities provided by the other Party.
- 24.4. The Contractor shall indemnify the Authority, their officers, servants and agents fully against any liability, loss, claim or proceedings whatsoever arising under this Contract or as a direct result of the Research in respect of:
- 24.4.1. any damage to property, real or personal, including any infringement of third party Intellectual Property rights, patents, copyright and registered designs; and,
 - 24.4.2. any injury to persons including injury resulting in death arising out of, or in the course of, or in connection with this Contract,
- except in so far as such damage or injury shall be demonstrated by the Contractor to be due to any act or neglect of the Authority, or their officers, servants or agents.
- 24.5. The Contractor shall promptly notify the Authority if any claim or demand is made or action brought against the Contractor for infringement or alleged infringement of Intellectual Property which might affect the Research and the Contractor shall discuss with the Authority the steps it proposes to take to keep the Authority informed of the progress in respect of such claims, demands or action.
- 24.6. Except in circumstances of fraud or willful misconduct by a Party or its affiliates, no Party or any of its affiliates shall be liable to another Party or any affiliate of the other 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 Contract.
- 24.7. Nothing in this Contract shall limit the liability of any Party in respect of:
- 24.7.1. personal injury or death arising out of that Party's negligence or willful misconduct; or
 - 24.7.2. fraud or fraudulent misrepresentation.

25. INSURANCE

- 25.1. Without prejudice to Clause 24.4, the Contractor shall throughout the duration of this Contract 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 Contractor arising out of the Contractor's performance of this Contract.
- 25.2. The Contractor shall produce on demand by the Authority documentary evidence that any insurance policies required by Clause 25.1 are in force.
- 25.3. The terms or the amount of cover of any insurance shall not relieve the Contractor

of any liabilities under the Contract. It shall be the responsibility of the Contractor to determine the amount of insurance that will be adequate to enable the Contractor to satisfy any liability referred to in Clause 24.4.

26. ASSIGNABILITY

- 26.1. Except as set out in Section 6, the Contractor shall not sub-contract, transfer or assign the whole or any part of this Contract without the prior written consent of the Authority, which consent may be subject to such terms and conditions as the Authority may specify. Approval of a Sub-contractor shall be signified by the inclusion of the name in Schedule B "Approved Sub-Contractors".
- 26.2. The Contractor shall be responsible for the acts and omissions of its Sub-contractors as though they were its own.
- 26.3. Notwithstanding Clause 26.1, the Contractor shall ensure that, to the extent that they are relevant, and where reasonable to do so, the terms of this Contract are incorporated into any Sub-contract (including any agreement with a Collaborator) and that all reasonable steps are taken by it to ensure that its Sub-contractors are aware of and adhere to the terms of this Contract.

27. SEVERABILITY

- 27.1. If any provision of this Contract is held invalid, illegal or unenforceable for any reason by any court of competent jurisdiction, such provision shall be severed and the remainder of the provisions hereof shall continue in full force and effect as if this Contract had been executed with the invalid provisions eliminated.
- 27.2. In the event of a holding of invalidity so fundamental as to prevent the accomplishment of the purpose of this Contract, the Parties shall immediately commence good faith negotiations to remedy such invalidity.

28. WAIVER

- 28.1. The waiver by the Authority of any right or remedy in respect of any breach of any term or condition or requirement of this Contract shall not prevent the subsequent enforcement thereof and shall not be deemed to be a waiver of any right or remedy in respect of any subsequent breach.

29. CORRUPT GIFTS OR PAYMENTS

- 29.1. The Contractor shall not do, and shall use all reasonable efforts to ensure that each Collaborator and any other party involved in the facilitation or performance of the Research does not do, (and the Contractor warrants that in entering the Contract it has not done) any of the following (referred to in this Clause as "prohibited acts"):
 - 29.1.1. offer, give or agree to give to any party (including but not limited to individuals, government authorities and corporate entities) any gift or consideration of any kind as an inducement or reward for doing or not doing (or having done or not having done) any act in relation to the obtaining or performance of this or any other contract with the Crown or the Research, or for showing or not showing favour or disfavour to any person in relation to this or any other contract with the Crown or that relates to the Research; and
 - 29.1.2. enter into this or any other contract relating to the performance of the Research in connection with which commission has been paid or has been agreed to be paid by it or on its behalf, or to its knowledge, unless

before that contract is made particulars of any such commission and the terms and conditions of any such agreement for the payment of it have been disclosed in writing to the Authority.

29.2. If the Contractor or any Collaborator, any of their employees, agents or any Sub-contractor, or anyone acting on its or their behalf, does any of the prohibited acts or commits any offence as the case may be under the UK Bribery Act 2010 with or without the knowledge of the Contractor, in relation to this or any other contract with the Crown that the Contractor is a party to, the Authority shall be entitled:

29.2.1. to terminate the Contract immediately by giving notice in writing to the Contractor and recover from the Contractor the amount of any loss resulting from the termination;

29.2.2. to recover from the Contractor the amount or value of any such gift consideration or commission; and

29.2.3. to recover from the Contractor any other loss sustained in consequence of any breach of this Clause, whether or not the Contract has been terminated.

29.3. In exercising its rights or remedies under this Clause, the Authority shall:

29.3.1. act in a reasonable and proportionate manner having regard to such matters as the gravity of the prohibited act, and the identity of the person performing the prohibited act, and, the nature of the procedures and precautions previously put in place by the Contractor to prevent such prohibited acts;

29.3.2. reserve the right to consult with an independent third party for advice and consideration of the case;

29.3.3. give all due consideration, where appropriate, to action other than termination of the Contract, including (without limitation to):

(a) requiring the Contractor to procure the termination of a Sub-contract where the prohibited act is that of a Collaborator or Sub-contractor;

(b) requiring the Contractor to procure the dismissal or removal from any involvement with any NIHR-funded Research of an employee (whether its own or that of a Collaborator or Sub-contractor) where the prohibited act is that of such employee.

30. FRAUD

30.1. The Contractor shall take all reasonable steps, in accordance with Good Industry Practice, to prevent Fraud in connection with the receipt of monies from the Authority by any of the Contractor (including where appropriate its shareholders, members, directors), the Contractor's employees, agents or sub-contractors, any Collaborator or Sub-contractor, or, any other party involved in the facilitation or performance of the Research.

30.2. The Contractor shall notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.

30.3. If the Authority receives allegations of Fraud or has reasonable grounds to believe that Fraud has been committed in relation to this or any other contract with the Crown (including the Authority) the Authority may:

30.3.1. investigate, or appoint a nominee to investigate, allegations received by

the Authority;

30.3.2. terminate the Contract immediately by giving notice in writing and recover from the Contractor the amount of any loss suffered by the Authority resulting from the termination, including the cost reasonably incurred by the Authority of making other arrangements for the supply of the Research and any additional expenditure incurred by the Authority throughout the remainder of the Contract Period; or

30.3.3. recover in full from the Contractor any other loss sustained by the Authority in consequence of any breach of this Clause 30.

30.4. In exercising its rights or remedies under this Clause, the Authority shall:

30.4.1. act in a reasonable and proportionate manner having regard to such matters as the gravity of the prohibited act, and the identity of the person performing the prohibited act, and, the nature of the procedures and precautions previously put in place by the Contractor to prevent such prohibited acts;

30.4.2. reserve the right to consult with an independent third party for advice and consideration of the case;

30.4.3. give all due consideration, where appropriate, to action other than termination of the Contract, including (without limitation to):

(a) requiring the Contractor to procure the termination of a Sub-contract where the prohibited act is that of a Collaborator or Sub-contractor;

(b) requiring the Contractor to procure the dismissal or removal from any involvement with any NIHR-funded Research of an employee (whether its own or that of a Collaborator or Sub-contractor) where the prohibited act is that of such employee.

31. DISPUTE RESOLUTION

31.1. Nothing in this Clause shall prevent a Party from seeking an interim injunction in any court of competent jurisdiction.

31.2. If any dispute, difference or question arises between the Parties with respect to any matter arising out of or relating to this Contract, the Parties shall first seek to resolve the dispute, difference or question shall be resolved in confidence by negotiation.

31.3. If the matter cannot be resolved through negotiation within one (1) month of the negotiations beginning, the Parties will, at the request of either of them, attempt in good faith to resolve the dispute through an agreed alternative dispute resolution ("**ADR**") procedure.

31.4. If the matter has not been resolved by an agreed ADR procedure within one (1) month of the initiation of such procedure, the dispute shall be referred to a single arbitrator to be agreed upon by the Parties or in default of agreement within fourteen (14) calendar days to be nominated by the President for the time being of the Chartered Institute of Arbitrators in accordance with the Arbitration Act 1996. The arbitration shall take place in London and shall be in accordance with the Arbitration Act 1996 and such arbitration rules as the Parties may agree or, in default of agreement, in accordance with the Rules of the London Court of International Arbitration which Rules are deemed to be incorporated by reference

into this Clause.

31.5. The decision of the arbitrator shall be final and binding on the Parties.

32. NOTICES

32.1. All notices to be given hereunder shall be in writing (which for these purposes does not include email) and may be served either personally at or by registered post to the address of the relevant Party as set out in Section 5, or as it may from time-to-time be notified in writing to the other Party and in the case of postal service shall be deemed to have been given three (3) calendar days after the day on which the notice was posted.

33. RELATIONSHIPS

33.1. This Contract does not make any Party the employee, agent, partner or legal representative of the other Party for any purpose whatsoever. No Party is granted any right or authority to assume or create any obligation or responsibility, expressed or implied, on behalf of or in the name of the other Party. In fulfilling obligations pursuant to this Contract the Contractor shall be acting as an independent contractor.

34. FREEDOM OF INFORMATION ACT 2000

34.1. The Parties are each subject to the requirements of the FOIA and the Environmental Information Regulations and shall assist and cooperate with each other at their own expense to enable the Parties to comply with these requirements. The Contractor shall (and shall procure that each Collaborator shall) comply with the provisions of this Clause 34 so that the Parties can comply with their obligations under the FOIA.

34.2. Where a Party receives a request for information under FOIA or the Environmental Information Regulations (“**Request for Information**”) in relation to information which it is holding on behalf of the other Party, it shall (and shall procure that its Sub-contractors shall):

34.2.1. transfer the Request for Information to the other Party as soon as practicable after receipt and in any event within two (2) Business Days of receiving a Request for Information;

34.2.2. provide the other Party with a copy of all information in its possession or power in the form that the other Party requires within five Business Days (or such other period as the Party may specify) of the Party’s requesting that information; and

34.2.3. provide all necessary assistance as reasonably requested by the Party to enable the Party to respond to a Request for Information within the time for compliance set out in section 10 of the FOIA or regulation 5 of the Environmental Information Regulations.

34.3. Where a Party receives a Request for Information which relates to the Contract, it shall inform the other Party of the Request for Information as soon as practicable after receipt and in any event within two (2) Business Days of receiving a request for information.

34.4. If the Party receiving the request determines that information (including Confidential Information) must be disclosed pursuant to Clause 34.3, it shall, if it is legally able to do so notify the other Party of that decision at least two (2) Business Days before disclosure.

34.5. The Party receiving the request shall be responsible for determining at its absolute discretion whether the Commercially Sensitive Information and/or any other Information:

34.5.1. is exempt from disclosure under the Code of Practice on Government Information, FOIA or the Environmental Information Regulations; and

34.5.2. is to be disclosed in response to a Request for Information.

34.6. Each Party acknowledges that the other Party may, acting in accordance with the Secretary of State's section 45 Code of Practice on the Discharge of the Functions of Public Authorities under Part 1 of the FOIA, be obliged under the FOIA or the Environmental Information Regulations to disclose Information:

34.6.1. without consulting with the other Party, or

34.6.2. following consultation with the other Party and having taken its views into account.

Provided always that where Clause 34.5.1 applies the Authority shall, in accordance with any recommendations of the Code, take responsible steps where appropriate, to give the Contractor advance notice, or failing that to draw to the Contractor's attention after any such disclosure.

35. TRANSPARENCY

35.1. The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA and or the Environmental Information Regulations, the content of this Contract is not Confidential Information. The Authority shall be responsible for determining in its absolute discretion whether any of the content of this Contract is exempt from disclosure in accordance with the provisions of the FOIA and or the Environmental Information Regulations.

35.2. The Authority may consult with the Contractor to inform its decision regarding any redactions but the Authority shall have the final decision in its absolute discretion.

35.3. The Authority may, at its sole discretion, redact information from the Contract prior to publishing for one or more of the following reasons:

35.3.1. national security;

35.3.2. personal data;

35.3.3. information protected by intellectual property law;

35.3.4. third party confidential information;

35.3.5. IT security; or

35.3.6. prevention of Fraud.

35.4. The Contractor shall assist and cooperate with the Authority to enable the Authority to publish this Contract.

35.5. Notwithstanding any other term of the Contract, the Contractor hereby gives consent for the Authority to publish the Contract in its entirety, including from time to time any agreed changes to the Contract, to the general public.

35.6. The Contractor acknowledges that the Authority supports the requirements of the IATI Standard and shall, at the Authority's reasonable request, provide all necessary assistance to enable the Authority to meet the IATI Standard which

shall include the provision of all information and data necessary for the transparent, accurate, timely and comprehensive publishing of all data on all activities related to the delivery of development co-operation and humanitarian aid.

36. UNLAWFUL DISCRIMINATION

- 36.1. The Contractor shall ensure that it complies with all current employment legislation and in particular, does not unlawfully discriminate within the meaning of the Equality Act 2010 or any other relevant local legislation relating to discrimination in the employment of employees, for the avoidance of doubt this includes having due regard, where so required, for any additional equality duties imposed on public authorities (collectively, the “**Employment Legislation**”).
- 36.2. The Contractor shall notify the Authority immediately of any investigation of or proceedings against the Contractor 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.
- 36.3. The Contractor shall indemnify the Authority 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 Contractor, its agents, employees or Sub-contractors.
- 36.4. The Contractor shall, and shall use reasonable endeavours to ensure that its employees or agents and/or Sub-contractors shall, at all times, act in a way which is compatible with the Convention rights with the meaning of Section 1 of the Human Rights Act 1998.

37. ODA

- 37.1. The Contractor acknowledges that it is the Authority’s intention that all monies paid to the Contractor will be properly categorised as ODA by the OECD.
- 37.2. The Contractor shall undertake reasonable endeavours to ensure that all monies paid to the Contractor can properly be categorised as ODA by the OECD.
- 37.3. The Contractor shall notify the Authority of any concern it has that monies paid to the Contractor cannot or may not be properly categorised as ODA by the OECD as soon as reasonably practicable.
- 37.4. If, as a consequence of the Contractor’s breach or negligent performance or nonperformance of this Contract, monies provided to the Contractor are not classified as ODA by the OECD, the Contractor shall repay to the Authority a sum equal to the amount which the OECD determines is not ODA. The exercise of the right under this clause 37.4 shall not affect the availability of any other remedy (contractual or otherwise) to the Authority.

38. SAFEGUARDING PROVISIONS

- 38.1. The Contractor shall:
- 38.1.1. take all reasonable steps to prevent actual, attempted or threatened Sexual Exploitation, Abuse or Harassment by its employees or any other persons engaged and controlled by it to perform any activities under this Contract; and
 - 38.1.2. adopt robust procedures for the reporting of suspected misconduct,

illegal acts or failures to investigate.

38.2. The Contractor shall take all reasonable steps to ensure that the Key Staff and others employed, retained or contracted by the Contractor to perform any activities under this Contract do not engage in sexual activity with any individual under the age of 18, even if the age of majority or age of consent is lower in the relevant territory.

38.3. The Contractor shall:

38.3.1. report any complaints or concerns regarding possible Sexual Exploitation, Abuse or Harassment by its employees or any other persons engaged and controlled by it to perform any activities under this Contract to the relevant authorities (including the Authority and local law enforcement or other agencies); and

38.3.2. take all reasonable steps to ensure that individuals are enabled to report concerns and complaints through supportive, confidential and accountable mechanisms.

38.4. The Contractor shall take all reasonable steps to investigate allegations or suspicions of Sexual Exploitation, Abuse or Harassment and take appropriate corrective action, including disciplinary action, against the Key Staff and others employed or retained by the Contractor to perform the Research, and will keep the Authority and relevant authorities informed of the progress of the investigations as appropriate.

38.5. In the event that the Contractor fails to comply with any of this Clause 38, the Authority reserves the right to:

38.5.1. deem this to be a material breach and terminate this Contract in accordance with Clause 20.3 herein; and/or

38.5.2. suspend or reduce its payment of amounts due under the payment schedule in Section 4 of this Contract; and/or

38.5.3. require repayment of all or part of the funding provided under this Contract; and/or

38.5.4. take a breach of this Clause 38 by the Contractor into account when considering future applications for funding from the Contractor.

38.6. For the avoidance of doubt, the Contractor shall:

38.6.1. obtain written confirmation from any Collaborator, and any subcontractor retained by the Contractor or by any Collaborator, subcontractors that they accept the standards set out in this Clause; and

38.6.2. ensure that all subcontracts reflect the terms and requirements of this Clause

in each case, prior to the Collaborator or other subcontractor performing any activity under this Contract.

38.7. For the purposes of this Clause 38:

38.7.1. Sexual Exploitation means any actual or attempted abuse of a position of vulnerability, differential power, or trust, for sexual purposes and includes but is not limited to profiting monetarily, socially, or politically from sexual exploitation of another.

38.7.2. Sexual Abuse means the actual or threatened physical intrusion of a

sexual nature, whether by force or under unequal or coercive conditions and includes but is not limited to all sexual activity with someone under the age of 18, regardless of local age of majority or consent.

38.7.3. Sexual Harassment means any unwelcome sexual advances (including but not limited to sexual advances made without touching) and includes but is not limited to requests for sexual favours, or other verbal or physical behaviour of a sexual nature, which may create a hostile or offensive environment.

39. EVALUATION

39.1. The Contractor shall and shall procure through a Collaboration Agreement that each Collaborator shall provide all reasonable co-operation and assistance necessary to allow the Authority to meet the Secretary of State for Health and Social Care's obligations under the International Development (Official Development Assistance Target) Act 2015 and the International Development (Reporting and Transparency) Act 2006. Such reasonable co-operation and assistance shall include but not be limited to:

39.1.1. the provision of all information requested by the Authority with the scope of the Research;

39.1.2. reasonable access to any of the Contractor and/or Collaborator's premises, records, data and to any equipment used (whether exclusively and non-exclusively) in the performance of the Research; and

39.1.3. access to the Contractor's personnel involved in the Research.

40. FURTHER ASSURANCE

40.1. The Contractor will, at the request of the Authority, do (or procure others to do) everything necessary to give the Authority the full benefit of this Contract.

41. CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999

41.1. No person who is not a party to this Contract is intended to receive a benefit under or have the right to enforce any terms of this Contract whether pursuant to the Contracts (Rights of Third Parties) Act 1999 or otherwise.

42. LAW

42.1. This Contract and any non-contractual obligations arising out of or in connection with it shall be considered as a contract made in England and be construed in accordance with the laws of England and Wales and subject to Clause 31 the Parties irrevocably submit to the exclusive jurisdiction of the courts of England.

SCHEDULE A: ASSIGNMENT

In consideration of the Authority's support for the Research detailed in the contract dated between the Contractor and the Secretary of State for Health and Social Care ("the Contract"), I/We[Contractor] hereby assign all Intellectual Property rights which exist now or come into existence in the future and to which I am / we are legally entitled in the Reports defined in the contract dated between myself / ourselves and the Secretary of State for Health and Social Care to the Secretary of State for Health and Social Care on behalf of the Crown.

Signed by:

Date:

Name in Block Capitals:

SCHEDULE B: COLLABORATORS AND SUB-CONTRACTORS

[INSERT]

SCHEDULE C: THIRD PARTY RIGHTS IN BACKGROUND IP INTRODUCED AT THE COMMENCEMENT OF THE RESEARCH

[INSERT]

SCHEDULE D: SCHEDULE OF ANTICIPATED FOREGROUND IP, ARISING KNOW HOW AND RESEARCH DATA ARRANGEMENTS

For use only in those contracts where the Contractor will not be the sole owner of arising Foreground IP, Arising Know How and/or Research Data and all/some of the same will be held by a Collaborator(s). This schedule should be used to set out at the Commencement Date all parties agreed intentions with regard to Foreground IP, Arising Know How and/or Research Data ownership and the resulting management and licensing mechanism to be put in place.

[INSERT]

SCHEDULE E: VARIATION TO CONTRACT FORM

Variation No: _____

Date: _____

1. The Contract is varied as follows:
2. Words and expressions in this Variation shall have the meanings given to them in the Contract.
3. The Contract, including any previous Variations, shall remain effective and unaltered except as amended by this Variation.

SIGNED:

For: The Authority
By:
Full Name:
Position:
Date:

For: The Contractor
By:
Full Name:
Position:
Date:

SECTION 3: RESEARCH

The Research is commissioned by the Authority using Official Development Assistance (ODA) funding.

[Insert the abstract of Contractor's application describing the specific work to be undertaken]

SECTION 4: FINANCIAL ARRANGEMENTS

1. Payment Arrangements

- 1.1. The total NIHR Funding to be paid by the Authority to the Contractor for the period of the Contract is shown in the payment schedule at Appendix 1 to this Section.

2. Financial Monitoring Arrangements

- 2.1. The Contractor is required to provide an annual report to the Authority in a format and containing information specified by the Authority and which will include a statement of expenditure in a format specified by the Authority.
- 2.2. If the total expenditure is less than the funding received by the Contractor, the funding for the subsequent financial year shall be reduced by this amount unless the Authority exercises a discretion not to require such reduction. The exercise of such discretion by the Authority is unfettered, but will, at a minimum, normally require the Contractor to demonstrate its requirement for the original funding in future years.
- 2.3. At the termination of the Contract the Authority will request a final expenditure statement. If the total expenditure is less than the funding received by the Contractor, this amount shall be recovered by the Authority.
- 2.4. If, in the opinion of the Authority, satisfactory progress has not been made against the Research objectives in Section 3 at any point during the period of the Contract payments may be withheld pending satisfactory resolution.

Appendix 1 to Section 4

PAYMENT SCHEDULE

It is intended that the indicated amounts will be paid by the Authority to the Contractor within thirty (30) calendar days of the dates listed.

[INSERT TABLE]

SECTION 5: KEY STAFF

Chief Investigator and address

[INSERT]

The Contractor's representative name and address

[INSERT]

The Authority's Representative, Contracting Issues name and address

Dr. Kay Pattison

Section Head, Research Programmes & Contracts

Science, Research and Evidence Directorate

Department of Health and Social Care

Quarry House

Quarry Hill

Leeds LS2 7UE

The Authority's Representative, Programme Management name and address

[Insert representative and address as required]

SECTION 6: REPORTING SCHEDULE

The reporting schedule is set out in the following table. Note that the quarterly report (QM1) contents will be based on the agreed schedule of milestones and deliverables provided on form MD1. A completed MD1 form will need to be attached to this contract.

Reporting Milestone(s)

Reporting Milestone	Reporting Milestone Date
First quarterly progress check-in (QM1) and financial expenditure (QSTOX) Reports	Within SIX months of the Commencement Date
Subsequent QM1 and QSTOX Reports	Every Three months after the first interim Report
Annual narrative report	Annually (date to be confirmed in relation to project start date)
Annual financial report	Annually (date to be confirmed in relation to project start date)
Final report	At project close (date to be confirmed)

If the above Reporting Milestones are not met, the Authority will consider the viability of the Research. This may result in funding being suspended or discontinued.

The Reports shall comply with any ODA reporting requirements as may be specified from time-to-time.