

**RESEARCH CONTRACT**

**BETWEEN**

**SECRETARY OF STATE FOR HEALTH (1)**

**AND**

**«Host Institution»(2)**

Version number: 6/12

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## SECTION 1: FORM OF CONTRACT

**This Form of Contract is made by and between**

**THE SECRETARY OF STATE FOR HEALTH** of Richmond House, 79 Whitehall, London,  
SW1A 2NS ("the Authority")

and

**«Host Institution», «Host Institution Legal Address Line»** ("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 will host **«Lead Applicant» - «Grant Reference»** to complete a **«Grant Type»** in accordance with the research and training programme specified in Section 3.
2. The Authority will pay the Contractor the Approved Cost as set out in Section 4 in respect of undertaking the Research and the Contractor's assignment of copyright and rights in the nature of copyright in the Material to the Authority on behalf of the Crown made pursuant to Conditions 15 and 17 of Section 2.
3. This Form of Contract (Section 1) together with the attached Sections 2 to 6 inclusive are the documents which collectively form the "Contract" (as defined in Section 2).
4. Where the Contractor is a health service body within the meaning of section 9 of the National Health Service Act 2006 then this Contract is an NHS Contract within the meaning of that Act.
5. 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.....

For the Contractor:

SIGNATURE.....

FULL NAME.....

POSITION HELD.....

ON BEHALF OF THE CONTRACTOR

DATE.....

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**SECTION 2: TERMS AND CONDITIONS**

## CONDITIONS OF AGREEMENT

### 1. DEFINITIONS AND INTERPRETATION

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

"Approved Cost"	means the total cost agreed for the Research as set out in Section 4.
"Authority's Representative"	means a person authorised to represent the Authority in respect of this Contract as identified in Section 5.
"Award"	means the award letter addressed to the Contractor together with the grant conditions which set out the terms and conditions governing the funding of the Research by the Authority.
"Business Day"	means a day other than Saturday, Sunday and bank holidays in London.
"Care Services"	means in: England – NHS and adult Social Care; Wales – NHS and Social Care; Scotland – NHS; Northern Ireland – Health and Social Care.
"Chief Investigator"	<i>means the individual identified in Section 3.</i>
"Collaborator"	means a person or organisation who works with the Contractor on the Research being done under this Contract subject to Condition 15.6.
"Commencement Date"	Means <b>«Grant Start Date»</b> notwithstanding the last day of signature of this Contract.
"Completion Date"	Means <b>«Grant End Date»</b> .
"Confidential Information"	means information of any form, however conveyed and irrespective of the media on which it is stored, that is:

	<p>(a) information which has been designated as confidential by either Party; or</p> <p>(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</p> <p>(c) Personal Data and sensitive personal data within the meaning of the Data Protection Act 1998; or</p>
<p>"Contract"</p>	<p>means the contract concluded between the Parties, consisting of the following Sections:</p> <p>Section 1 : Form of Contract</p> <p>Section 2 : Terms and Conditions</p> <p>Section 3 : Research</p> <p>Section 4 : Financial Arrangements</p> <p>Section 5 : Key Staff.</p> <p>Section 6 : Reporting Schedule</p>
<p>"Contractor Background IP"</p>	<p>means:</p> <p>(a) any Intellectual Property owned by the Contractor and identified as being required for the undertaking of the Research at the Commencement Date; and</p> <p>(b) any Intellectual Property created, devised or generated by the Contractor's staff (including visiting researchers) <i>working in the research</i></p>



	<i>group of and/or supervised by the Chief Investigator during the term of, the Research (other than Foreground IP) which is used in the performance of the Research.</i>
"Contractor's Collaboration Agreement"	<i>Means the agreement(s) between the Contractor and its Collaborators who are party to delivering the Research.</i>
"Contractor's Representative"	means the person authorised 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.
"Data"	means information which is either Personal Data or non-Personal Data collected and/or used for the purposes of the Research set out in this Contract which can be processed manually, electronically or by other means.
"Default"	means any breach by a Party to this Contract of its obligations under this Contract (including but not limited to a fundamental breach or breach of a fundamental term) or any default, act, omission, negligence or statement of a Party to this Contract or its employees, agents or sub-contractors in connection with or in relation to the subject matter of this Contract and in respect of which such Party is liable to another.
"Drop Dead Date"	Means [INSERT DATE] the last date by which work on doing the Research must have started.
"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 Intellectual Property that is, or has been created, exemplified or developed (whether in whole or in part) during the course and for the purpose of the Research including for the avoidance of doubt Foreground IP generated by a Collaborator.
"Fraud"	means any offence under Laws creating offences in respect of fraudulent acts or at common law in respect of fraudulent acts in relation to the Contract or defrauding or attempting to defraud or conspiring to defraud the Crown.
"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
"Insolvency Event"	means where a Party: <ul style="list-style-type: none"> <li>(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 therefrom effectively agrees to be bound by or assumes the obligations imposed on that other party under this Contract);</li> <li>(b) has an encumbrancer 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</li> </ul>

	<p>appointment of a receiver or similar officer over all or any part of its assets or undertaking;</p> <p>(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;</p> <p>(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;</p> <p>(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;</p> <p>(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;</p> <p>(g) ceases or threatens to cease to carry on business;</p> <p>(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</p> <p>(i) anything analogous to any of the</p>
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	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 (including in know-how) 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.]
"Material"	means any report, executive summary, paper, abstract or other document provided by the Contractor under Conditions 13 and 14. For the avoidance of doubt this means the copyright in such reports, summary and papers but shall not extend to Results, Foreground IP or other Intellectual Property described therein.
"NIHR TCC"	Means :  National Institute for Health Research, Trainees Co-ordinating Centre Leeds Innovation Centre 103 Clarendon Road Leeds LS2 9DF
"Personal Data"	has the meaning ascribed to it in the Data Protection Act 1998.
"Project"	means the Research together with the

	Results.
"Research"	means the scope of work specified in Section 3.
"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.
"Results"	means any Data or information generated by the Research.
"Third Party IP"	means any Intellectual Property which is owned by a third party other than the Contractor but where the Contractor can reasonably expect to secure a formal agreement or license to use in the Research at the Commencement Date, or to gain formal usage rights in accordance with the provisions of this Contract prior to the commencement of, or during the term of, the Research.
"Variation"	means a variation to this Contract agreed and executed in accordance with Condition 6.

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

1.2.1 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 Sections and Schedules are to sections of and schedules to this Contract and references to Conditions are references to conditions in the Section of this Contract in which they appear, unless otherwise stated;

1.2.3 where the context allows, references to male gender include the female gender and the neuter, and the singular includes the plural and vice versa;

- 1.2.4 references to a Party shall include that Party's personal representatives, successors or permitted assignees;
- 1.2.5 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
- 1.2.6 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 Condition 2.2 or to earlier termination in accordance with its terms, shall continue in full force and effect until the Completion Date.
- 2.2 If in the Authority's reasonable opinion, the Research has not effectively commenced by the Drop Dead Date or by such other date as the Parties may agree in writing, the Authority may withdraw the Award and/or any offer of funding and this Contract will terminate.

## 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 details of the non-confidential research plan and project costs.
- 3.3 The Contractor shall ensure that each member of staff engaged on the Research undertakes to observe the Conditions of this Contract and any further or supplementary Contract entered into between the Parties hereto and that 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 Condition 19, the Authority may terminate this Contract with immediate effect at any time if any member of the Contractor's Key Staff is not available to fulfil his 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 to be followed and the day-to-day responsibility for carrying out this programme will be under the

control of the Contractor, in consultation, as appropriate, with the Authority's Representative.

- 3.6 The Contractor shall ensure full communication takes place between the Parties and such others as may be notified to the Contractor by the Authority and the Contractor shall advise the Authority as required on the Research. In particular the Contractor must notify the Authority and the relevant research ethics committee of any proposed deviation from the agreed protocol or if significant developments occur as a study progresses, including developments in relation to the safety of individuals or to scientific direction.
- 3.7 The Authority reserves the right to terminate this Contract with immediate effect 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 which case no financial compensation shall be payable to the Contractor.

**Where collaboration arrangements predate the research application**

- 3.8 Where the Research involves Collaborators, the Contractor shall submit to the Authority a signed copy of the Contractor's Collaboration Agreement. This shall be submitted to the Authority's Representative at the commencement of the Research.

**Where collaboration arrangements have not yet been formally agreed**

- 3.9 Where the Research involves Collaborators, the Contractor shall submit to the Authority a draft copy of the Contractor's Collaboration Agreement prior to signature by the Contractor. This shall be submitted to the Authority's Representative within a timeframe to be agreed.

**3A. PERFORMANCE IN INITIATING AND DELIVERING CLINICAL RESEARCH**

Initiating Clinical Research

- 3A.1 The Authority wishes to see a dramatic and sustained improvement in the performance of providers of NHS services in initiating clinical research.
- 3A.2 The Contractor shall measure, for every clinical trial that it hosts and irrespective of the funder, the duration in days from the time when the Contractor's designated representative(s) receives a Valid Research Application for a trial, to the time when the Contractor recruits the first patient for that trial.
- 3A.3 The Contractor shall publish the name and the Research Ethics Committee Reference Number of every clinical trial for which it gave NHS permission in the preceding four Quarters together with the duration specified in Condition 3A.2.

The Contractor shall publish this information within Thirty (30) days of the end of each Quarter in a publicly accessible part of their website.

- 3A.4 The Contractor shall submit the information specified in Condition 3A.3 to the Authority in an electronic format specified by the Authority within 30 days of the end of each Quarter. For any trial where the duration specified in Condition 3A.2 exceeds an initial NIHR benchmark for trial initiation of 70 days, the Contractor shall explain the reason for the variance to the Authority.
- 3A.5 This Clause is intentionally left blank.
- 3A.6 The Authority shall publish, on the website of the National Institute for Health Research, the information on trial initiation that it has received from the Contractor as a provider of NHS services under this Contract.
- 3A.7 If the Contractor fails to meet the NIHR benchmark for trial initiation for two successive Quarters, and the Authority considers the Contractor's explanations for this to be unsatisfactory, the Authority reserves the right to suspend its payment of amounts due under the payment schedule in Section 4 of the Contract (Financial Arrangements) until such time as the Contractor has demonstrated that it has met the benchmark for a Quarter. In enforcing this Condition, the Authority shall act in a reasonable and fair way taking into consideration factors that are outside the control of the Contractor.
- 3A.8 Repeated failure to meet the NIHR benchmark for trial initiation shall be taken into account by the Authority when considering applications from the Contractor where the Contractor seeks NIHR funding and may have a negative effect on such applications. In enforcing this Condition 3A.8, the Authority shall act in a reasonable and fair way taking into consideration factors that are outside the control of the Contractor.
- 3A.9 The Authority wishes to see a dramatic and sustained improvement in the performance of providers of NHS services (including the Contractor) in delivering clinical research to time and target and increasing the overall number of patients in trials and in so doing the Authority will initially focus on the delivery of commercial contract clinical trials.
- 3A.10 The Contractor shall publish in a publicly accessible part of the Contractor's website, the name and Research Ethics Committee Reference Number of every commercial contract clinical trial that it hosts, together with:
- a. the Target Number of patients it has agreed to recruit to that trial;
  - b. the time that it has agreed it would take to recruit the Target Number of patients; and
  - c. whether trial recruitment by the Contractor is ongoing or finished; and



d. if trial recruitment by the Contractor has finished, whether or not the agreed Target Number of patients was recruited within The Agreed Time.

The Contractor shall publish this information within Thirty (30) days of the end of each Quarter in a publicly accessible format on their website.

3A.11 The Contractor shall submit the information specified in Condition 3A.10 to the Authority in an electronic format specified by the Authority within Thirty (30) days of the end of each Quarter.

3A.12 The Authority shall publish, on the website of the National Institute for Health Research, the information on delivering clinical research to time and target that it has received from the Contractor (as a provider of NHS services) under this Contract.

Additional support provided by the Authority

3A.13 The Authority has established a framework of good practice and standard procedures called NIHR Research Support Services. The use of NIHR Research Support Services by providers of NHS services will enable those providers to stop unnecessary duplication of regulatory reviews and improve their performance in initiating and delivering clinical research to time and target. Providers of NHS services (including the Contractor) that use NIHR Research Support Services will have access to NIHR financial support for these activities.

#### 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 its payment of amounts due under this payment schedule at any time if in the view of the Authority reasonable progress on the Research has not been maintained, or if reports have not been submitted as required under Condition 13. Subject to these limits the Contractor is free to administer the funds within the terms of this Contract without further reference to the Authority.

4.2 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 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.

- 4.3 The Contractor is responsible for payments to third parties and shall ensure that such payments are made promptly.
- 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 31<sup>st</sup> 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 Condition 4.3.1, a new payment schedule will be issued with the Approved Cost adjusted accordingly.”
- 4.4 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.
- 4.5 The Contractor shall not make any change in the total remuneration, conditions of service or numbers of staff engaged on the Research which will require a change in the total amount payable, or make material changes to the Research detailed in Section 3, without prior written approval being given by the Authority.
- 4.6 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 for the duration of the Research Period and for a period of six (6) years after the end of the Research Period.
- 4.7 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 and integrity in connection therewith.
- 4.8 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:
- 4.8.1 the Research has been completed to the satisfaction of the Authority;

- 4.8.2 the reports required under Conditions 13 and 14 have been submitted by the Contractor to the Authority, and the Authority shall not unreasonably withhold or delay approval;
- 4.8.3 agreement has been reached in respect of any items remaining for disposal.
- 4.9 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.
- 4.10 The Authority shall be under no obligation to make any payment on claims received more than TWELVE (12) months after the completion of the Research 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, 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.
6. **VARIATION**
- 6.1 If at any time it appears likely that any provision of the Contract, in particular the Research, needs to be varied the Contractor shall immediately 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. Upon receipt of such a request the Authority may:
- 6.1.1 agree to vary the Contract;
- 6.1.2 vary the Research in a manner which the Contractor agrees can be carried out within the Research Period and Approved Cost;
- 6.1.3 refuse the request and require the continuation of the Research in accordance with the Contract; or
- 6.1.4 give notice of termination in accordance with Condition 19.
- 6.2 Any variation to the Contract shall be set out in a Variation to Contract Form as set out at Schedule B to this Section 2 and signed by 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 Contractor's 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 staff. 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 & 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 shortlisting 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 Contractor's 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 publish the Results in appropriate research journals.
- 7.5 Subject to Condition 9, the Contractor shall cause to be kept full, detailed and accurate records of all of activities and results obtained in connection with the Project. In this respect, the Contractor shall and shall procure that the staff and Collaborators and sub-contractors 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 Project and the results of such research, development and other work, including keeping bound note books with page numbering recording all results and observations signed by the persons obtaining such results or making such observations, and countersigned appropriately.
- 7.6 The Contractor shall upon request make available to the Authority copies of all records generated in connection with the Project, including for the avoidance of doubt, records generated by Staff or Collaborators or Approved Sub-contractors under Condition 7.5 and by any third parties working on the project pursuant to Condition 15.6.

7.7 In the event of the awardee having changed employers to become a new employee of the Contractor, as a result of taking up this award in order to pursue a career as part of their clinical academic career pathway, certain accrued occupational benefits which are linked to continued HEI or NHS service of employment shall be protected by the contractor. These rights include, but not limited to, all family care related leave (irrespective of gender or sexual orientation), annual leave and sick leave (irrespective of disability status or health history).

## 8. **PUBLICITY**

8.1 Before and after the start of the Research Period, and prior to the publication of the Research, Foreground IP, Results or Data or of matters arising from the Results or Data in accordance with Condition 17, the Contractor shall not without the prior written consent of the Authority, which shall not be unreasonably refused 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 condition 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 In the event that the Contractor fails to comply with this Condition 8.1 the Authority reserves the right to terminate this Contract with immediate effect by notice in writing.

## 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 Condition 9, the receiving Party undertakes to keep secret and strictly confidential and shall 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 provided 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 be so construed as to 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 does not result in a disclosure of any Confidential Information or infringement of any valid Intellectual

Property Rights of either Party or the unauthorised processing of any Personal Data.

9.2 Condition 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 Condition 9.1);

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 is independently developed without access to the Confidential Information; or

9.2.5 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 Condition 32 (Freedom of Information).

9.3 The obligations of each of the Parties contained in Condition 9.1 above shall continue without limit of time. In the event that the Contractor fails to comply with this Condition 9, the Authority reserves the right to terminate this Contract with immediate effect by notice in writing.

## 10. **DATA PROTECTION**

10.1 The terms Data Controller and Data Processor shall have the same meaning as in the Data Protection Act 1998. Where the Contractor acts as a Data Processor for the Authority who acts as a Data Controller, it shall act in accordance with the Authority's instructions.

10.2 The Contractor undertakes to the Authority that, in relation to its performance of this Contract and/or as required for the proper and lawful operation of this Contract, it will comply with all applicable laws, regulations, orders and codes of practice from time to time in force relating to data protection.

10.3 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.

- 10.4 In addition, but without prejudice to the provisions of Condition 10.3, the Contractor agrees to treat any data obtained in connection with the Research from which a living individual is identifiable as Personal Data, in order to ensure that the data subjects to whom such information relates are afforded the data protection and privacy rights to which they are entitled.
- 10.5 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 Condition 23.5, 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.
- 10.6 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.
- 10.7 The Contractor shall ensure that medical information relating to the individuals who are the subjects of the Research shall be used in accordance with:
- 10.7.1 the Medical Research Council's "Personal Information in Medical Research", as amended from time to time; and
  - 10.7.2 "The NHS Confidentiality Code of Practice", guidelines on the use and protection of patient information, as amended from time to time.
- 10.8 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.
- 10.9 Both Parties shall comply with their respective obligations under the Data Protection Act 1998 in the performance of this Contract.
- 10.10 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 relevant applicable laws and the terms of this Condition 10.

10.11 The Contractor shall, from time to time, comply with any reasonable request made by the Authority to ensure compliance with the measures of these data protection clauses and any relevant and applicable data protection and/or privacy laws.

10.12 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 DATA**

11.1 Subject to the provisions of Condition 10, the Authority reserves the right to have access to and to use Data compiled during the course of the Research and will respect existing guidance on confidentiality of any Data which it obtains.

11.2 The Contractor shall, at the request of the Authority, deposit both qualitative and quantitative Data in a relevant data archive subject to any reasonable delay necessary to enable the protection or exploitation of Foreground IP.

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

## 12. **RESEARCH PRACTICE AND ETHICS**

12.1 The Contractor will ensure that research in any way connected with this Contract is conducted in accordance with the Department of Health guidance "Research Governance Framework For Health and Social Care", with "The Concordat to support Research Integrity" and, if relevant, in accordance with the Department of Health guidance "Governance Arrangements for Research Ethics Committees ("GAfREC") or such other guidelines as may be issued from time to time by the Department of Health or the Health Research Authority and copies of which are made available to the Contractor.

12.2 The Contractor shall comply with all relevant legislation including but not limited to:

12.2.1 The Medicines for Human Use (Clinical Trials) Regulations (SI2004/1031) as Amended;

12.2.2 The Human Tissue Act 2004; and



12.2.3 The Mental Capacity Act 2005.

12.3 Unless any of the exceptions or other exclusions described in GAfREC apply, the Contractor will submit the Research for review by a Research Ethics Committee recognised by the Authority if the Research proposed involves:

12.3.1 potential research participants (including those who have died within the last 100 years) identified from, or because of, their past or present use of the Care Services (including Care Services provided under contract with the private or voluntary sectors), including participants recruited through these Care Services as healthy controls;

12.3.2 potential research participants (including those who have died within the last 100 years) identified because of their status as relatives or carers of past or present users of Care Services;

12.3.3 collection of tissue (i.e. any material consisting of or including human cells) or information from users of Care Services;

12.3.4 use of previously collected tissue or information from which individual past or present users of Care Services could be identified, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, the possession of someone to whom the tissue or information is made available;

12.3.5 xenotransplantation;

12.3.6 prisoners; or

12.3.7 social care;

with a view to obtaining the Research Ethics Committee's favourable opinion of the Research and will inform the Authority's Representative when such favourable opinion has been given (whether unconditionally or subject to conditions) or withheld.

12.4 Research activity requiring ethical approval shall not commence until such favourable opinion is given.

### 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 3.

13.2 The Contractor shall procure that the Fellow shall provide an interim written report on the progress of the Research according to the schedule set out in Section 6. The interim report 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 and shall detail all Data, methods, Results, Background and Foreground IP and provisional conclusions together with management information and any other relevant information relating to the Research up to the relevant date.

- 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.

14. **FINAL REPORT AND RESEARCH OUTPUTS INFORMATION**

- 14.1 The Contractor shall provide a final report on the Research within SIX (6) WEEKS of the Completion Date or date of termination howsoever terminated. The final report shall be in a form to be agreed with the Authority as amended from time to time or as otherwise required by the Authority's Representative and shall include the Data, methods, Results and final conclusions 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 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 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 annual research outputs information collected through NIHR-authorized web-based systems.

- 14.5 The Authority reserves the right to reproduce the findings of the final report or to provide a summary of the findings.

15. **INTELLECTUAL PROPERTY RIGHTS**

- 15.1 The Contractor will identify, protect and maintain Intellectual Property in accordance with its standard institutional policy ("Contractor IP Policy"). The Contractor will make available a copy of the Contractor IP Policy on the request of the Authority.

- 15.2 Foreground Intellectual Property that may arise from the Research shall either vest in the Contractor, or shall be managed in accordance with the Contractors Collaboration Agreement, pursuant to Condition 3.8 and Schedule D and periodically updated pursuant to Condition 13.2.

- 15.3 The Contractor shall make available the Contractor Background IP that is necessary or useful for undertaking the Research and the protection, dissemination or exploitation of the Foreground IP. Where it is reasonable to do so and is an appropriate means of achieving the public benefit, the Contractor has responsibility for filing, prosecuting, maintaining, defending and enforcing protection for such Contractor Background IP, and shall retain this responsibility unless otherwise agreed in writing and in any event at no cost to the Authority. If the Contractor wishes to cease doing so in relation to any of such Contractor Background IP necessary for the dissemination, use or exploitation of the Foreground IP, it shall notify the Authority no less than THREE (3) months prior to discontinuing its maintenance, defence or enforcement of such Background IP and, subject to the prior rights of third parties, the Authority shall have the right but not the obligation to take over responsibility for such Contractor Background IP. Where such Contractor Background IP is unencumbered by third party rights, the Contractor shall licence or assign the Contractor Background IP to a nominee of the Authority's choosing free of charge, in all other cases, such licence or assignment shall be made on fair and reasonable terms.
- 15.4 The Contractor shall use reasonable endeavours to make available the Third Party IP that is necessary or useful for undertaking the Research and the protection or exploitation of the Foreground IP.
- 15.5 Subject to the prior rights of third parties and the Contractor having made reasonable efforts to overcome them the Contractor shall grant (and shall procure that all Collaborators grant) to the Authority a non-exclusive, irrevocable, royalty-free, worldwide licence together with the right to grant sub-licences to:
- 15.5.1 use and publish (in accordance with Condition 17) any information which is not Confidential Information, Intellectual Property, Results, Materials and conclusions arising from the Research for academic and non-commercial research purposes and for evaluation, teaching and training purposes relating to the provision of care and treatment of both NHS patients and NHS funded patients; and
  - 15.5.2 use the Contractor's Background IP and Third Party IP but solely to the extent that it is necessary to use any information, Intellectual Property, Results, Materials and conclusions arising from the Research for the purposes described in sub-Condition 15.5.1 above.
- 15.6 The Contractor shall not enter into any Collaboration Agreements in which the Intellectual Property arrangements would adversely affect the Contractor's ability to comply with the terms of this Contract without the prior consent of the Authority, such consent not to be unreasonably withheld or delayed.

16. **EXPLOITATION OF INTELLECTUAL PROPERTY**

16.1 The Contractor shall inform the Authority of any Results, including any Intellectual Property, whether patentable or not, which are capable of exploitation either by direct adoption into the healthcare service or via commercialisation in a timely manner.

16.2 The Contractor shall develop, implement and maintain procedures for the management of Intellectual Property in the Results and in particular, but without limitation, shall use all reasonable endeavours to ensure that:

16.2.1 the Foreground IP is identified and recorded;

16.2.2 it notifies the Authority within SIX (6) months of receipt of disclosure of potential patentable Foreground IP and in the event that the Contractor decides not to protect the invention by filing a patent application, the Contractor 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 may reasonably request an extension of up to one (1) year from the date of any such notification under this Condition 16.2 to enable further validation or development of the Foreground IP prior to protection;

16.2.3 prior to any publication of the Results of the Research, patentable inventions arising from the Results are identified, duly considered for patentability and, where it is commercially reasonable to do so and is an appropriate means of achieving the public benefit, patent applications are filed in respect thereof at patent offices in territories where products or services arising from the inventions may be made, sold or used in accordance with the Contractor IP Policy;

16.2.4 in exercising the rights in Condition 16.2 the Contractor takes due consideration of the Authority's attitude to access to essential 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);

16.2.5 in exercising the rights in Condition 16.2 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;

- 16.2.6 all such patent applications are diligently prosecuted having regard to all relevant circumstances; and
  - 16.2.7 in the event that the Contractor elects to abandon prosecution of a patent application protecting applications of the Results of the Research, the Contractor shall inform the Authority's Representative at least three (3) 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.
- 16.3 The Contractor shall permit the Authority to monitor the operation and effectiveness of the Contractor's procedures for the management of Intellectual Property in such ways as the Authority considers reasonably necessary to ensure that any Foreground IP generated is disseminated and/or exploited for the public 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 records kept pursuant to Condition 16.4.3, 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.
- 16.4 Consistent with the good management of Intellectual Property and subject to the written agreement of the Authority, the Contractor shall use all reasonable endeavours to:
- 16.4.1 where reasonable and practicable, promote the dissemination of the Results to maximise the benefits to the NHS, patients and the public;
  - 16.4.2 where reasonable and practicable, exploit commercially such Results to generate either capital or revenue or both; and
  - 16.4.3 Pursuant to Condition 7.6 keep proper records showing the description of the Contractor Background IP or Third Party Background IP used and Foreground IP generated.
- 16.5 The Contractor shall or shall procure that *any* Collaborator shall seek the prior written consent of the Authority before it *or any Collaborator, as the case may be*, makes any commercial use of, or grants to any third party any exploitation rights over the Foreground IP. The Authority shall not unreasonably withhold or delay such consent, but as a condition of granting consent, the Contractor shall or shall procure that any Collaborator shall provide all appropriate details of any

proposed commercialisation arrangements, including but not limited to any deal sheet or commercial terms in circulation, which information the Authority shall keep confidential. The Authority shall within thirty (30) Business Days of such a written consent request inform the Contractor and/or Collaborator if the Authority requires the Contractor and or Collaborator] to enter into a commercialisation agreement with the Authority. Any such commercialisation agreement shall take into consideration the relative contribution of the Authority, the Contractor, Collaborators and other third party funders or contributors to the Foreground IP.

- 16.6 In the event that the Contractor and/or Collaborator decides to seek approval for commercialisation under Condition 16.5, then the Contractor and/or Collaborator] must 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 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).
- 16.7 If the Contractor 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 Condition 19.4, then the Authority shall have the right, acting reasonably and subject to the rights of third party licencees 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 notice in writing that it is failing to protect, manage and exploit such Foreground IP to the Authority's reasonable 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 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.
- 16.8 If the Contractor wishes to use any third party (excluding its professional advisors) to carry out its obligations with respect to this Condition 16, which is different from that proposed in the Contractor IP Policy, 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.

16.9 The Authority may, by notice in writing, require the Intellectual Property to be promptly assigned to the Authority if the Contractor is subject to an Insolvency Event.

16.10 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. **PUBLICATION**

17.1 The Contractor must notify the Authority's Representative prior to any publication (whether in oral, written or other form) of the Research or Foreground IP or Results or Data or of matters arising from such Results or Data. The Contractor shall send one draft copy of the proposed publication to the Authority's Representative at the same time as submission for publication or at least 28 days before the date intended for publication whichever is earlier. For the avoidance of doubt this obligation continues after the end of the Research Period.

17.2 In the event that the Contractor fails to comply with Condition 17.1 the Authority reserves the right to terminate this Contract by notice in writing with immediate effect.

17.3 Subject to the provisions of Condition 9 and notwithstanding the provisions of Condition 15 and 16, the Authority's Representative may at any time publish the Material for any non-commercial purpose and in conjunction with the Authority's statement on Open Access to research "Statement on DH/NIHR-funded research and Europe PubMed Central". Such purposes may include 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.

17.4 The Contractor shall assign to the Authority on behalf of the Crown all Intellectual Property rights in the Material 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.

17.5 The Contractor undertakes to obtain an assignment to the Authority of any Intellectual Property rights in the Material 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.

- 17.6 The Authority will ensure that any Queen’s Printer and Controller of HMSO copyright publication arising from the Material carries the following statement:

“© Queen’s Printer and Controller of HMSO 20xx [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”.

- 17.7 The Contractor shall ensure that the outcome of the Research is prepared for publication in a suitable peer-reviewed journal and shall ensure that it, and any other publication, including patent applications, of or resulting from research carried out under this Contract shall acknowledge 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 report is independent research supported by the National Institute for Health Research («**Grant Type**», «**Lead Applicant**», «**Grant Reference**»). 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.”

18. **NIHR FACULTY**

- 18.1 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 Faculty.

- 18.2 The Contractor shall inform the Authority immediately of any suspension or termination of employment of any staff providing services in connection with this Contract.

- 18.3 The Contractor shall make reasonable efforts to ensure that individuals employed to provide services in connection with this Contract abide by the rules, regulations and codes of conduct of their employer; of their professional regulatory bodies where applicable; with relevant guidance published by the Authority on the conduct of research; and with guidance on membership of NIHR Faculty set out on the NIHR website in the document “Faculty membership: Benefits and Responsibilities”.

19. **TERMINATION UPON OCCURRENCE OF EVENTS**

- 19.1 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 Condition 19.1, 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.

- 19.2 The Authority will not pay any sum under Condition 19.1 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.
- 19.3 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 there is a change of control (as defined by sections 450 and 451 of the Corporation Taxes Act 2010) in Contractor. The Authority shall be permitted to exercise its rights pursuant to this Condition 19.3 for only six (6) months after any such change of control and shall not be permitted to exercise such rights where the Authority has agreed in advance in writing to the particular change of control and such change of control takes place as proposed. The Contractor shall notify the Authority within two (2) weeks of any change of control taking place.
- 19.4 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:
- 19.4.1 the approvals sought pursuant to Condition 12 are not given unconditionally within TWELVE (12) months of the commencement of the Research Period; or
- 19.4.2 the Contractor is in material breach of any of the terms and conditions of this Contract, and:
- (a) in the case of a breach capable of remedy, it fails to remedy that breach within thirty (30) days of the service of a written notice by the Authority specifying the breach and requiring its remedy; or
- (b) where the authority then makes other arrangements for the provision of the Research, the Authority is entitled to recover from the contractor the cost of making those other arrangements, or
- (c) the breach is not capable of remedy; or
- 19.4.3 an event of Force Majeure, as defined in Condition 22 exists for more than six (6) months; or

19.4.4 any provision of this Contract (other than as previously specified in the preceding provisions of this Condition 19) expressly entitles the Authority to terminate this Contract; or

19.5 Termination of this Contract by the Authority under the preceding provisions of this Condition 19 shall (at the option of the Authority) terminate this Contract with immediate effect as from the date of service of the notice of that termination or from the expiry of such period (not exceeding six (6) months) specified in that notice.

## 20. **CONSEQUENCES OF TERMINATION**

20.1 Termination of this Contract, however caused, shall not:

20.1.1 release the Contractor from any duty or obligation of confidence, in particular as imposed by Conditions 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

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

## 21. **EQUIPMENT**

21.1 The Contractor shall take all practical steps to purchase all materials and equipment at a fair and reasonable price. The Authority may inspect the original quotations and invoices issued to the Contractor 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.

21.2 At the end of the Research Period, and after the final presentation of the Results all equipment purchased for use on the Research with funds provided by the Authority shall become the property of the Contractor.

## 22. **FORCE MAJEURE**

22.1 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.

22.2 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.

22.3 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.

22.4 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. **WARRANTIES AND LIABILITY**

23.1 The Contractor warrants that:

23.1.1 it has the requisite capacity and authority and all necessary licences, permits and consents to enter into this Contract;

23.1.2 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;

23.1.3 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,

23.1.4 to the best of its knowledge and belief:

(a) subject to the declaration set out in Schedule C it is the legal and beneficial owner of all right, title and interest in and to the Contractor Background IP;

(b) it and/or a Collaborator will be the legal and beneficial owner(s) of all right, title and interest in and to the Foreground IP and where reasonable and practicable the Collaborator will own and manage such Foreground IP in accordance with, and subject to the terms of this Contract; and

- (c) it has not granted any third party any right in respect of the Foreground IP (other than in accordance with the provisions of this Contract), and has not charged or encumbered and will not charge or encumber any of the same.
- 23.1.5 the Research will be carried out by appropriately experienced, qualified and trained personnel with all due skill, care and diligence;
- 23.1.6 no research activity requiring ethical approval will commence until such favourable ethical approval is given. In particular, but without limitation, recruitment of potential research participants will not commence until such favourable ethical approval is given; and
- 23.1.7 the Contractor will discharge its 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.
- 23.2 Except as expressly provided in this Contract, none of the Parties gives any warranties or makes any representations 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 that any material produced or supplied by any Party and any processes or techniques used, proposed or recommended by any Party will not infringe the Intellectual Property rights of any person in any country. Notwithstanding any other provision of this Agreement, each Party shall use its reasonable endeavours to mitigate losses it may incur that are covered by indemnities provided by the other Party.
- 23.3 Subject to Condition 23.5 the Contractor shall indemnify the Authority, its officers, servants and agents fully against any liability, loss, claim or proceedings whatsoever arising under any statute or at common law in respect of:
  - 23.3.1 any damage to property, real or personal, including any infringement of third party Intellectual Property rights; and,
  - 23.3.2 any injury to persons including injury resulting in death arising out of, or in the course of, or in connection with this Contract,excepting 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.
- 23.4 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 rights 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.

23.5 Except in circumstances of fraud or wilful misconduct by a Party or its affiliates, no Party or any of its affiliates shall be liable to another Party or any affiliate of another party for special, indirect, incidental or consequential damages, whether in contract, warranty, negligence, tort, strict liability or otherwise, arising out of any breach of or failure to perform any of the provisions of this Contract.

23.6 Nothing in this Contract shall limit the liability of any Party in respect of:

23.6.1 personal injury or death arising out of that party's negligence or wilful misconduct; or

23.6.2 fraud or fraudulent misrepresentation.

#### 24. **ASSIGNABILITY**

24.1 Except as set out in Section 3, the Contractor shall not sub-contract, transfer or assign the whole or any part of this Contract or collaborate with any third party in the performance of its obligations under 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.

24.2 The Contractor shall be responsible for the acts and omissions of its sub-contractors as though they were its own.

24.3 Notwithstanding Condition 24.2, the Contractor shall ensure that, to the extent that they are relevant, and where reasonable to do so, the Conditions of this Contract are incorporated into any sub-contract and that all reasonable steps are taken by it to ensure that its sub-contractors are aware of and adhere to the Conditions of this Contract.

#### 25. **SEVERABILITY**

25.1 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.

25.2 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.

#### 26. **WAIVER**

26.1 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.

27. **CORRUPT GIFTS OR PAYMENTS**

27.1 The Contractor shall not do (and warrants that in entering the Contract he has not done) any of the following (referred to in this clause as "prohibited acts"):

27.1.1 offer, give or agree to give to any servant of the Crown 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 for showing or not showing favour or disfavour to any person in relation to this or any other contract with the Crown;

27.1.2 enter into this or any other contract with the Crown in connection with which commission has been paid or has been agreed to be paid by him or on his behalf, or to his knowledge, unless before the 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.

27.2 If the Contractor, his employees, agents or any sub-contractor, or anyone acting on his or their behalf, does any of the prohibited acts or commits any offence as the case may be under the Bribery Act 2010 with or without the knowledge of the Contractor, in relation to this or any other contract with the Crown, the Authority shall be entitled:

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

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

27.2.3 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.

27.3 In exercising its rights or remedies under this clause, the Authority shall:

27.3.1 act in a reasonable and proportionate manner having regard to such matters as the gravity of, and the identity of the person performing the prohibited act;

27.3.2 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 sub-contractor;

- (b) requiring the Contractor to remove from association with the Research an employee (whether his own or that of a sub-contractor) where the prohibited act is that of such employee.

28. **FRAUD**

- 28.1 The Contractor shall take all reasonable steps, in accordance with Good Industry Practice, to prevent Fraud by Contractor's Staff and the Contractor (including its shareholders, members, directors) in connection with the receipt of monies from the Authority.
- 28.2 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.
- 28.3 If the Contractor or Contractor's Staff commits Fraud in relation to this or any other contract with the Crown (including the Authority) the Authority may:
  - 28.3.1 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 Research Period; or
  - 28.3.2 recover in full from the Contractor any other loss sustained by the Authority in consequence of any breach of this Condition 28.

29. **DISPUTE RESOLUTION**

- 29.1 Any dispute, difference or question between the Parties with respect to any matter arising out of or relating to this Contract shall be resolved by negotiation.
- 29.2 If the matter cannot be resolved through negotiation, 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.
- 29.3 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) 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 Condition.

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

30. **NOTICES**

31.1 All notices to be given hereunder shall be in writing 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 3 working days after the day on which the notice was posted.”

31. **RELATIONSHIPS**

31.1 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.

32. **FREEDOM OF INFORMATION ACT 2000**

32.1 Each Party acknowledges that the other Party is subject to the requirements of the FOIA and the Environmental Information Regulations 2004 and each Party shall assist and cooperate with the other (at their own expense) to enable the other Party to comply with these information disclosure obligations.

32.2 Where a Party receives a request for information under FOIA or the Environmental Information Regulations (“Requests 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):-

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

32.2.2 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

32.2.3 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.

32.3 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 Business Days of receiving a request for information.

32.4 If either Party determines that Information (including Confidential Information) must be disclosed pursuant to Condition 33.3, it shall notify the other Party of that decision at least two Business Days before disclosure.

32.5 Each Party shall be responsible for determining at its absolute discretion whether the Commercially Sensitive Information and/or any other Information:-

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

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

32.6 Each Party acknowledges that the other Party may, acting in accordance with the former Department of Constitutional Affairs' Code of Practice on the Discharge of Functions of Public Authorities under Part I of the Freedom of Information Act 2000, be obliged under the FOIA or the Environmental Information Regulations to disclose Information:-

32.6.1 without consulting with the other Party, or

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

32.7 Each Party acknowledges that any lists or schedules provided by it outlining Confidential Information, are of indicative value only and that the other Party may nevertheless be obliged to disclose Confidential Information in accordance with Condition 33.6.

### 33. **TRANSPARENCY**

33.1 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.

33.2 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.

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

- 33.3.1 national security;
  - 33.3.2 personal data;
  - 33.3.3 information protected by intellectual property law;
  - 33.3.4 third party or Collaborator confidential information;
  - 33.3.5 IT security; or
  - 33.3.6 prevention of fraud.
- 33.4 The Contractor shall assist and cooperate with the Authority to enable the Authority to publish this Contract.
- 33.5 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.
34. **UNLAWFUL DISCRIMINATION**
- 34.1 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 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**").
- 34.2 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.
- 34.3 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.
- 34.4 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.

35. **FURTHER ASSURANCE**

35.1 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.

36. **CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999**

36.1 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.

37. **LAW**

37.1 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 Condition 30 the parties irrevocably submit to the exclusive jurisdiction of the courts of England.

**SCHEDULE A: ASSIGNMENT**

I/We .....[Contractor] hereby assign all Intellectual Property rights to which I am / we are legally entitled in the Material defined in the contract dated ..... between myself / ourselves and the Secretary of State for Health to the Secretary of State for Health on behalf of the Crown.

Signed by: .....

Date: .....

Name in Block Capitals: .....

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**SCHEDULE B: VARIATION TO CONTRACT FORM**

Project Title :

Project Application No:

Contract between the Secretary of State for Health ("the Authority") and [ ]

("the Contractor") dated \_\_\_\_\_ ("the Contract")

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

For: The Contractor

By:.....

By:.....

Full Name:.....

Full Name:.....

Position:.....

Position:.....

Date: .....

Date:.....

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

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## **SCHEDULE D: SCHEDULE OF ANTICIPATED FOREGROUND IP ARRANGEMENTS**

For use only in those contracts where the contractor will not be the sole owner of arising Foreground IP, and all/some Foreground IP 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 ownership and the resulting management and licensing mechanism to be put in place.

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**SECTION 3: RESEARCH**

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## **SECTION 4: FINANCIAL ARRANGEMENTS**

### **PAYMENT SCHEDULE**

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

#### **«Payment Schedule Table»**

An appropriate inflation uplift may be added by the Authority to these payments.

The Contractor will be required to submit an annual statement of expenditure detailing the actual expenditure incurred (on a fully accrued basis) in the 12 month period ending 31<sup>st</sup> March throughout the duration of the award.

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.

Upon conclusion of the Research, the Contractor shall submit a Final Statement of Expenditure to the Authority, accounting for all costs properly incurred under the Contract. Only upon receipt of this document, and with agreement from the Authority's Representative, will the final payment of any outstanding funds be made. Should the total funds provided to the Contractor exceed the amount stated in the Final Statement of Expenditure the Authority will seek to recover the excess funds from the Contractor.

«Budget Table Html»

## SECTION 5: KEY STAFF

«Lead Applicant»

«Lead Applicant Address New Line»

[The Contractor's Representative for project management purposes]

**INSERT NAME AND ADDRESS OF RESEARCH CONTRACT OFFICER**

[The Contractor's Representative for contract management purposes]

*Dr Kay Pattison*

*Research and Development Directorate*

*Department of Health*

*Quarry House*

*Quarry Hill*

*Leeds LS2 7UE*

[The Authority's Representative for contract management purposes]

«Grant Manager Fullname»

*NIHR Trainees Co-ordinating Centre,*

*Leeds Innovation Centre,*

*103 Clarendon Road*

*Leeds*

*LS2 9DF*

[The Authority's Representative for project management purposes]

## SECTION 6: REPORTING SCHEDULE

The interim report schedule is set out in the following table:

Report	Due date
First interim report	Within [INSERT NUMBER] months of the Commencement Date
<i>[EITHER: Subsequent interim reports</i>	<i>Every [INSERT NUMBER] months after the first interim report</i>
<i>OR: Second interim report</i>	<i>Within [INSERT NUMBER] months of the Commencement Date AND SO ON]</i>

## REFERENCES

Medical Research Council's Personal Information in Medical Research

<http://www.mrc.ac.uk/news-events/publications/personal-information-in-medical-research/>

Statement on DH/NIHR-funded research and Europe PubMed Central

<http://www.nihr.ac.uk/policy-and-standards/nihr-policy-on-open-access-for-its-funded-research.htm>

NIHR Faculty

<http://www.nihr.ac.uk/faculty/Pages/default.aspx>

The NHS Confidentiality Code of Practice

<https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice>

Governance Arrangements for NHS Research Ethics Committees

<https://www.gov.uk/government/publications/health-research-ethics-committees-governance-arrangements>

Research Governance Framework For Health and Social Care

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4108962](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962)