RESEARCH CONTRACT

BETWEEN

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE (1)

AND

KHEIRON MEDICAL TECHNOLOGIES LTD (2)

Version number: 1/20

AI Health and Care Award – Phase 4

CONTENTS

SECTION 1 FORM OF CONTRACT

This Form of Contract is made by and between

THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE of 39 Victoria Street, Westminster, London, SW1H 0EU

(the "**Authority**")

and

KHEIRON MEDICAL TECHNOLOGIES LTD a company incorporated and registered in England and Wales with company number 10184103 whose registered office is at 2nd Floor Stylus Building, 116 Old Street, London, England, EC1V 9BG (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 undertake a research and evaluation project entitled '*Mia Real World Testing*' in accordance with the work specified in SECTION 3 and including the Deliverables and the Service Support elements (as defined in SECTION 2 and detailed in SECTION 3 (having regard to the pre-amble to that SECTION 3 and Part D thereof)), together, the "**Research**".

2. The Authority will pay the Contractor the Approved Cost in accordance with and as set out in SECTION 4 in respect of undertaking the Research in accordance with this Contract, and the Contractor's assignment of copyright and rights in the nature of copyright in the Reports to the Authority on behalf of the Crown delivered pursuant to Conditions 13 and 14 of SECTION 2.

3. This Form of Contract (SECTION 1) together with the attached SECTION 2 to SECTION 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.

The remainder of this page is left blank intentionally.

Signature page to Form of Contract

For the Authority:

SIGNATURE…… [redacted] ……

FULL NAME…… [redacted] ……

POSITION HELD…… Director of Policy & Strategy, NHSX ……

ON BEHALF OF THE AUTHORITY

DATE…… 11/27/2020 ……

For the Contractor:

SIGNATURE…… [redacted] ……

FULL NAME…… [redacted] ……

POSITION HELD…… Chief Technology Officer ……

ON BEHALF OF THE CONTRACTOR

DATE…… 11/25/2020 ……

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:

"Applicable Law"	means: (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 applicable binding court order, judgment or decree; (d) 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.
"Approved Cost"	means the total cost agreed for the Research as set out in SECTION 4.
"Arising Know How"	means Know How that is created, devised or generated by or on behalf of the Contractor or any Collaborator exclusively during the course and for the purpose of the Research, and which relates solely to Foreground IP. For the avoidance of doubt, "Arising Know How" excludes any Know How relating to, comprised within or constituting Contractor Background IP.
"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 dated 8 September 2020.
"Background IP"	means any Intellectual Property and/or, unpatented, technical and other practical information or Know How which is not in the public domain (including information comprising or relating to concepts, Inventions, ideas, discoveries, data, formulae, research models, analytics, methodologies, assessments

	specifications, methods, research plans, procedures for experiments and tests and results of experimentation and testing) in existence at the Commencement Date or created, devised or generated other than solely and exclusively 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.
"Care Services"	means in: England – NHS and adult Social Care; Wales – NHS and Social Care; Scotland – NHS and adult Social Care; Northern Ireland – Health and Social Care.
"Collaborator"	means a person or organisation who works with the Contractor on the Research being done under this Contract and that is listed at SECTION 3, Part B.
"Commencement Date"	means 08 September 2020 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 or any other commercial basis; (c) any use in support of the development, promotion or provision of Health Care direct to an individual on a fee paying basis; or (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), which is beyond the scope of the Contractor's or Collaborator's (as applicable) business as currently

	conducted, as conducted prior to the Commencement Date or as contemplated by the officers or other relevant staff of the Contractor or Collaborator (as applicable). In the context of the Contractor, "Commercial Use" is expressly noted to exclude any use or exploitation for or in the context of the development, provision and exploitation of medical imaging analysis related technologies and/or services.
"Completion Date"	means 30 September 2023.
"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, including Special Categories of Personal Data, within the meaning of those terms in Data Protection Legislation; 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 SECTION 3: RESEARCH SECTION 4: FINANCIAL ARRANGEMENTS SECTION 5: KEY STAFF SECTION 6: REPORTING SCHEDULE

"Contractor Background IP"	means any Background IP that is owned, controlled or used under licence by the Contractor or a Collaborator. "Contractor Background" includes: (a) Mia™ and any new, improved or augmented AI algorithms, models, model weights or other results of calibrations of such algorithms or models created or generated under or in connection with the Research, including as a result of any part of the Research and/or in respect of use and deployment of Mia™ at any Research Site; and (b) any derivative, development, improvement, modification or augmentation of Mia™ (including any data or derivatives of data therein) or any other Contractor Background IP; and (c) any information comprising or relating to concepts, Inventions, ideas, discoveries, data, formulae, research models, analytics, methodologies, assessments specifications, methods, research plans, procedures for experiments and tests and results of experimentation and testing – in each case in the field of, or relating to, medical imaging or scans (including x-rays (such as mammograms), computed tomography imaging, digital breast tomosynthesis imaging, and any so-called 'multimodality imaging'), that arises or is conceived, created, devised, generated, exemplified or reduced to practice by, or by a person on behalf of, the Contractor or Collaborator in the course of or in connection with the Research, or independently of the Research.
"Contractor's Collaboration Agreement"	means the agreement(s) between the Contractor and its Collaborators who are party to collaborating in respect of the Research.

"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 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.
"Deliverables"	means those outcomes relating to the Research that are noted in SECTION 3, Part C (as are to be the subject of the Variation described in SECTION 3, Part D).
"Deployment Agreement"	an agreement relating to the deployment and operation of Mia™ at a Research Site, based on the then-current form of the Contractor's standard terms and conditions for its provision of Mia™ to its customers (having regard to the nature of the relevant deployment – e.g., an 'on-premise' of 'Software-as-a-Service' based deployment), amended by the Contractor for use in connection with the Research and the Study to be conducted at that Research Site (including, for example, to reflect the details outlined in Condition 3.8 and provision of the Service Support to that Research Site).
"Drop Dead Date"	means 8 March 2021 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 exclusively during the course and for the purpose of the Research, and is wholly and absolutely distinct and severable from Contractor Background IP, and does not constitute a derivative, development, improvement, modification or augmentation of the Contractor Background IP. As an example of the limited category of Intellectual Property intended to constitute "Foreground IP", it includes such Intellectual Property as may be developed exclusively during the course and for the purpose of the Research, which does not relate to any elements of Mia™ and relates solely and uniquely to a Research Site's proprietary software or systems, such as the NHS Breast Screening System with which Mia™ may be connected in performance of the Research.
"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 applicable 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.

"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 therefrom effectively agrees to be bound by or assumes the obligations imposed on that other party under this Contract);

(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 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
	(i) 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, any other rights in or to data, 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.
"Invention"	means any invention, idea, discovery, development, improvement or innovation (whether or not patentable or capable of registration, and whether or not recorded in any medium).
"Know How"	has the meaning given to it in Commission Regulation (EU) 316/2014 of 21 March 2014 at Article 1, 1(i).
"Mia™"	means the Contractor's deep learning mammography intelligent assessment system (a.k.a. Mia™) including all software, algorithms, data, models and technology making up the same.
"Patient Benefit"	means achieving any one or more of the following:
	(a) identifiable improvements in the quality of treatment and clinical care offered by any Health Service Body;

	(b) identifiable improvements in the experience of patients receiving care from any Health Service Body; (c) identifiable improvements in patient health outcomes; (d) identifiable improvements in the efficiency of any Health Service Body; (e) identifiable and measurable cost savings in any Health Service Body; (f) generating revenue for any Health Service Body; or (g) any other outcome that has been accepted in writing by the Authority and that is designed to benefit any Health Service Body or a significant number of patients receiving Health Care from any Health Service Body.
"Persistent Service Support Default"	means the Persistent Service Support Default to be agreed pursuant to Part C and Part D of SECTION 3.
"Personal Data"	has the meaning ascribed to it in the Data Protection Legislation.
"Project Research"	means the research conducted or carried out by Contractor and/or any Collaborator in performance of the Research relating to health economic analysis and evaluation, patient and/or clinician experience and satisfaction concerning the deployment of Mia™ and/or the conduct of the Studies at Research Sites.
"Reports"	means, together, the interim report delivered pursuant to Condition 13.1 and the final report delivered pursuant to Condition 14.1 (excluding any drafts thereof), and "**Report**" shall mean one of them. For the avoidance of doubt this does not extend to Background IP, Foreground IP, Research Data or other Intellectual Property or Know How described, summarised or referenced therein.
"Research"	has the meaning given to that term in SECTION 1

"Research Data"	means information or data (which is not Personal Data, but which may be a de-identified derivative of Personal Data) that is collected or generated in the performance of, and relates primarily to, the Project Research and includes (but is not limited to) information that is collated or stored in searchable form and any and all derivatives of any such information or data. For the avoidance of doubt, Research Data does not include information or data that has been analysed or any data that is otherwise comprised within Contractor Background IP or Foreground IP.
"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.
"Research Site"	means any NHS Trust site at which a Study will be performed.
"Service Support"	means any services outlined in SECTION 3 that are to be provided by or on behalf of the Contractor to support the performance of the Research, and are labelled in Part C of SECTION 3 as, and/or agreed pursuant to Part D of SECTION 3 to be, "Service Support".
"Sensitive Material"	means information, data or other content that may or may reasonably be expected to prejudice the Contractor's, any Collaborator's or its licensors' Intellectual Property (including any Background IP, Foreground IP or Arising Know How) or any right, title or interest therein or thereto, and/or its or its licensors' protection of its Confidential Information (including trade secrets) and/or unpatented, technical and other practical information or Know How which is not in the public domain (including information comprising or relating to concepts, Inventions, ideas, discoveries, data, formulae, research models, analytics, methodologies, assessments specifications, methods, research plans,

	procedures for experiments and tests and results of experimentation and testing).
"State Aid Legislation"	means any and all legislation of the United Kingdom and the European Union (for so long as it has direct effect in the laws of the United Kingdom) regarding the provision of state aid.
"Study"	means a Study, to be conducted at a Research Site, that forms part of the Research, as detailed in SECTION 3.
"Third Party IP"	means any Intellectual Property which is owned or controlled by any party (including any Collaborator) other than the Contractor, which is used in the performance of the Research or to perform the provisions of this Contract, and over which the Contractor has or can reasonably expect to secure an agreement, permission or licence to use in the performance of the Research or to perform the provisions of this Contract for the required purpose.
"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 references to Conditions in Sections of this Contract are illustrative only and shall not be determinative of whether or not a term of this Contract is classified as a 'condition', a 'warranty' or 'innominate term';

1.2.6 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

1.2.7 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 Condition 19, shall continue in full force and effect until the Completion Date.

2.2 If no part of the Research has 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, PERFORMANCE AND DIRECTION OF RESEARCH

3.1 It is noted that research commissioned by the Authority is open and, subject to the provisions of this Contract, details of research such as the Project Research are normally published, provided that that any such publication may only be effected subject to and in accordance with Condition 18.

3.2 The Authority may publish details of the non-confidential research plan and project costs subject to and in accordance with Condition 18.

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 agreement 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 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.

3.5 The Contractor shall endeavour to ensure that full communication takes place between the Parties and such other persons as may reasonably be notified to the Contractor (e.g., any 'evaluator'), and shall provide the Authority with status updates on the progress of the Research in accordance with reporting schedules agreed in accordance with SECTION 6. 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.

3.6 Where the Research involves Collaborators, the Contractor shall submit to the Authority a copy of the Contractor's Collaboration Agreement for reference (which may be provided in redacted form, with any confidential or commercially sensitive information removed). This shall be submitted to the Authority's Representative within a timeframe to be agreed.

3.7 In respect of those elements of the Research relating to deployment of Mia™ at a Research Site the Contractor shall enter into a Deployment Agreement with the Research Site prior to commencement of that element of the Research relating to deployment of Mia ™ at such Research Site (including the relevant Study).

3.8 It is noted and agreed that use of Mia™ under a Deployment Agreement shall be at no cost to the relevant Research Site only insofar as it relates to 'preliminary testing' and conduct of the relevant 'study' at that Research Site (as those terms or similar or equivalent concepts are more particularly described and defined in the relevant Deployment Agreement).

3.9 The Contractor shall comply with and adhere to any reasonable compliance, governance or security standards, procedures or protocols reasonably required by the relevant Research Site (as and where applicable and having regard to the nature of the relevant Study and Mia™ (including the manner of the relevant deployment – e.g., an 'on-premise' of 'Software-as-a-Service' based deployment)).

3.10 The Contractor shall perform the Research and complete the Deliverables in accordance with the details and provisional timeline recorded in SECTION 3, Part B and Part C.

3.11 The Contractor shall provide the Service Support in accordance with the standards and timelines recorded in SECTION 3, Part C

3.12 The Authority shall perform its obligations in SECTION 3 (in particular Part D thereof) with a view to facilitating the successful performance of the Research.

4. ACCOUNTING AND PAYMENTS

4.1 The Authority shall pay the Approved Cost during the Research Period in accordance with dates and amounts specified in SECTION 4 within 30 days of receipt of an invoice from the Contractor for the relevant amount. The Authority may suspend its payment of amounts due under this payment schedule if, and only for so long as, the Authority can demonstrate that:

4.1.1 there is a Persistent Service Support Default;

4.1.2 the interim Report has not been submitted as required under Condition 13; or

4.1.3 Contractor has materially failed to comply with the terms of this Contract.

4.2 Subject to Condition 4.1, the Contractor is free to administer the funds received pursuant to that Condition within the terms of this Contract without further reference to the Authority.

4.3 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 x 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.

4.4 The Contractor is responsible for payments to third parties and shall ensure that such payments are made promptly. In particular, where the Contractor is required to make payments to a Health Service Body, such payments will be made within 30 days of receipt of an invoice that is validly issued under the agreement governing and conditioning such payments.

4.5 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.

4.6 Without limiting Condition 4.3, 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 Approved Cost, or make material changes to the Research detailed in SECTION 3, without prior written approval being given by the Authority.

4.7 Subject to the Authority having first provided not less than ten (10) Business Days' prior notice, the Contractor shall grant 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 relating to the Research, and/or other information relating to such 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.

4.8 The Contractor shall provide all reasonable cooperation and assistance at all times during the Research Period 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.

4.9 On completion of the Research Period, the final payment of the Approved Costs (and any other 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:

4.9.1 the Research has been completed in accordance with the terms of this Contract; and

4.9.2 the Reports required under Conditions 13 and 14 have been submitted by the Contractor to the Authority.

4.10 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.

4.11 The Authority shall be under no obligation to make any payment on claims received more than twelve 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.

4.12 The Contractor is subject to the additional clauses set out in SCHEDULE E: STATE AID, and the Authority hereby warrants and represents that it has no reason to believe that any payment made hereunder constitutes State Aid.

4.13 All amounts payable by the Authority under the Contract are exclusive of amounts in respect of value added tax chargeable from time to time ("**VAT**"). Where the Contractor makes any taxable supply for VAT purposes to the Authority under the Contract (a "**Supply**"), the Authority shall, on receipt of a valid VAT invoice from the Contractor, pay to the Contractor such additional amounts in respect of VAT as are chargeable in respect of such Supply at the same time as payment is due for the relevant Supply (as determined by this Contract, including Condition 4.1 and SECTION 4). Any such VAT invoice shall show the VAT calculations as a separate line item.

5. SET OFF

If any sum of money shall be due from the Contractor to the Authority, 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.

6. VARIATION

6.1 If at any time a Party becomes aware that any provision of the Contract, in particular the Research, needs to be varied, that Party shall promptly notify the other Party 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 Party receiving such request and proposals may:

6.1.1 agree to vary the Research);

6.1.2 vary the Research in a manner which the Contractor agrees can be carried out within the Research Period and Approved Cost; or

6.1.3 refuse the request and require the continuation of the Research in accordance with the Contract.

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 and only if and to the extent relevant having regard to the nature of the Research, 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 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 (if and as relevant in the context of the particular staff, their role on the Research, and the relevant aspects of the Research), and the Authority acknowledges that any such terms and conditions may preclude publication, dissemination, open sourcing or disclosure of any Sensitive Materials.

7.4 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 Research. In this respect, the Contractor shall and shall procure that the staff and Collaborators and Research Sites and sub-contractors shall at all times observe professional standards.

8. NOT USED

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 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 commits a material breach in failing to comply with this Condition 9, the Authority reserves the right to terminate this Contract in accordance with Condition 19.3.2.

10. DATA PROTECTION

Compliance

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 comply, and is responsible entering into agreements with each Collaborator and any Research Site containing appropriate terms relating to compliance, with the directly applicable requirements and obligations of the Data Protection Legislation in the performance of the Research including:

10.1.1 completing all appropriate data protection impact assessments before commencing the relevant elements of the Research;

10.1.2 putting in place all appropriate data processing agreements, which may, in the context of the deployment and use of Mia™ be based upon the form attached to the Deployment Agreement; and

10.1.3 making available any data or information reasonably required in order to fulfil transparency or other obligations under the Data Protection Legislation (including in respect of automated decision making).

10.2 Subject to the Authority having first provided not less than ten (10) Business Days' prior notice, the Authority may within normal business hours request the Contractor to provide reasonable evidence in order to enable it to ascertain compliance with the Data Protection Legislation in relation to the Research and the terms of this Condition 10.

Confidentiality and security

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 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.

10.5 The Contractor shall ensure that medical information relating to the individuals who are the subjects of the Project 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 In performing the Research, the Contractor shall, and shall use reasonable endeavours to procure that any Collaborator and Research Site, as and where applicable, adhere to the following:

10.6.1 DHSC Code of Conduct for Data Driven Technology, setting out Government's expectations for the development, deployment and use of data driven technology as updated from time to time

(available here: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology as at the date of drafting);

10.6.2 NHSX's Digital Health Technology Standard, setting out how suppliers can develop digital health technologies in a manner which enables accelerated review and commissioning into the NHS as updated from time to time

(available here: https://www.nhsx.nhs.uk/media/documents/NHS_Digital_Health_Technology_Standard_draft.pdf as at the date of drafting);

10.6.3 NICE Evidence Standards Framework for Digital Health Technologies, describing standards for the evidence that should be available, or developed, for digital health technologies to demonstrate their value in the UK health and care system

(available here: https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf as at the date of drafting);

10.6.4 Govt Security Classifications describing HM Government's administrative system for the secure, timely and efficient sharing of information

(available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/715778/May-2018_Government-Security-Classifications-2.pdf as at the date of drafting).

10.7 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 23.6, 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, excepting in so far as such circumstances can be demonstrated by the Contractor to be due to any act or neglect of the Authority, or their officers, servants or agents

10.8 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.

10.9 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 The Authority shall not be entitled to inspect, take or be supplied with copies of the Research Data other than in an anonymised form as set out in the outline provided in the Reports.

11.2 The Contractor shall ensure that all basic factual data is either pseudonymised or de-identified (as the Contractor determines appropriate in the circumstances) 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 pseudonymisation satisfies the appropriate standard recommended by the Information Commissioner's Office from time to time.

11.3 In the event that, the Contractor does supply the Authority with:

11.3.1 Personal Data (including Personal Data that has been pseudonymised) the Contractor warrants to the Authority that any Personal Data provided (whether by way of reporting progress or results or otherwise) has been provided under a valid legal basis for the purposes of the Data Protection Legislation; and/or

11.3.2 Personal Data that has been pseudonymised or anonymised before being provided, the Contractor warrants to the Authority that it has been pseudonymised or anonymised to the appropriate standard recommended by the Information Commissioner's Office from time to time,

and, where relevant, the Contractor further warrants that any Personal Data (including Personal Data that has been pseudonymised) may be used by the Authority for the purposes for which it is disclosed, subject to the Authority's compliance with Data Protection Legislation in relation to use for such purpose (e.g., in relation to its transparency obligations and obligations to establish a valid legal basis for the processing concerned).

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 Health Research Authority guidance "UK Policy Framework For Health and Social Care Research", with "The Concordat to support Research Integrity" and, if relevant, in accordance with the Health Research Authority 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 and Social Care 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 The Contractor shall use (and shall use reasonable endeavours to procure that each Collaborator and Research Site shall use) all reasonable endeavours to comply with guidance and advice from the Authority and the Health Research Authority on research governance and the use and implementation of the Authority model research agreements or those issued by Health Research Authority where possible, which may be issued from time to time.

12.4 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:

12.4.1 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;

12.4.2 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;

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

12.4.4 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;

12.4.5 xenotransplantation;

12.4.6 human DNA extracted from acellular material;

12.4.7 prisoners; or

12.4.8 social care;

with a view to obtaining the Research Ethics Committee's favourable opinion of the Research.

12.5 Any element(s) of the Research requiring ethical approval of the Health Research Authority shall not commence until such favourable opinion is given – the Contractor will provide the Authority's Representative with a copy of the Research Ethics Committee's favourable opinion and the Health Research Authority approval once they have been given (whether unconditionally or subject to conditions) or inform the Authority's Representative if either is withheld.

12.6 Any element(s) of the Research activity requiring ethical approval shall not commence until such favourable opinion is given.

12.7 In the event of any animals being used in research, all requirements of the Animals (Scientific Procedures) Act 1986 must be followed. In addition, the Department of Health and Social Care's mission statement and Home Office advice on ethical review process in relation to this Act must be effective and in operation.

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 (including progress as to attainment of the Deliverables and the Service Support) and SECTION 6.

13.2 The Contractor shall provide an interim written report on the progress of the Project 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 agreed by the Parties, and shall detail an outline of provisional conclusions relating to management and financial information relating to the costs and progress of the Research, health economic analysis and evaluation, patient and/or clinician experience and satisfaction relating to the deployment of Mia™ and/or the conduct of the Studies at Research Sites.

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 as agreed in the meetings referred to in SECTION 6.

13.4 During the Research Period, the Contractor shall regularly gather feedback from Research Sites and report such feedback to the Authority. This feedback:

13.4.1 shall as a minimum address the issues listed at SECTION 6; and

13.4.2 may be gathered by any appropriate means including by using questionnaires offered to individuals (whether Research Site staff or other participants in the Research (including the Project Research)) and by offering such individuals other opportunities to provide feedback.

13.5 Under no circumstances shall anything in this Condition 13 or elsewhere in this Contract operate to require the Contractor to include any Sensitive Material in any Report or otherwise.

14. FINAL REPORT

14.1 The Contractor shall provide a draft final report on the Project Research within sixty (60) Business Days of the Completion Date or within such longer period that is reasonable in the circumstances following the date of termination of this Contract (howsoever terminated). The draft final Report shall be in a form to be agreed with the Authority and shall include an outline of the Research Data and conclusions relating to management information and financial information relating to the costs and outcomes of the Research, health economic analysis and evaluation, patient and/or clinician experience and satisfaction relating to the deployment of Mia™ and/or the conduct of the Studies at Research Sites.

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 prepare and publish, or arrange for the preparation and publication of, such a report (which shall constitute Confidential Information; and may only be published subject to and in accordance with Condition 18).

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 Authority-authorised 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 subject to and in accordance with Condition 18.

14.6 Under no circumstances shall anything in this Condition 14 or elsewhere in this Contract operate to require the Contractor to include any Sensitive Material in any Report or otherwise.

15. INTELLECTUAL PROPERTY RIGHTS

15.1 Nothing in this Contract operates to transfer any rights in or to any Contractor Background IP. As between the Parties, Contractor retains sole ownership of all right, title and interest, including all Intellectual Property rights, in and to the Background IP.The Contractor grants to the Authority a non-exclusive, personal, royalty-free licence during the Research Period to use its Contractor Background IP provided or made available to the Authority only to the limited extent strictly necessary for the Authority to perform its obligations in relation to the Research and under this Contract.

15.2 Nothing in this Contract operates to transfer any rights in or to any Foreground IP or Arising Know How. As between the Parties, Contractor retains sole ownership of all right, title and interest, including all Intellectual Property rights, in and to the Foreground IP and any Arising Know How, subject only to Condition 18.2. As between the Parties, any and all rights in and to the Foreground IP and any Arising Know How shall vest automatically upon its creation in, and shall be exclusively owned by, the Contractor.

15.3 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.

15.4 The Contractor shall ensure that 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:

15.4.1 the Contractor may not use, or permit any other party to use, the Arising Know How for any Commercial Use without having first notified the Authority in accordance with Condition 16.5;

15.4.2 the Contractor and Collaborator(s) may only use the Arising Know How in accordance with Condition 9.1.2.

15.5 The Contractor shall use reasonable endeavours to make available to the Collaborators and to the Authority the Third Party IP that it considers necessary for enabling the Authority or a Collaborator to perform their obligations in relation to the Research.

15.6 It is noted that the Authority may wish to take a licence from the Contractor to use certain Foreground IP and/or Arising Know How – and the Parties agree that any such use shall be subject to terms and conditions (including, but not limited to, terms and conditions relating to the duration, nature and scope of such licence, liability, audit provisions, termination, governing law and jurisdiction, provision of royalties and/or other appropriate form of remuneration which is fair and reasonable, and/or the apportionment of expenses incurred in securing Intellectual Property protection in respect of relevant Foreground IP and/or Arising Know How) to be agreed by and between the parties under an arms-length agreement which may be negotiated and entered into by and between the Parties.

15.7 The Contractor shall grant (and shall use reasonable efforts to procure that all Collaborators and Research Sites grant)to the Authority a non-exclusive, royalty-free, worldwide licence to use:

15.7.1 any information relating to the Research which is not Confidential Information of the Contractor;

15.7.2 any Foreground IP;

15.7.3 Research Data;

15.7.4 Arising Know How; and

15.7.5 conclusions arising from the Research,

in each case only if and as summarised in the Reports, for the limited purpose of publishing the Reports subject to and in accordance with Condition 18.

15.8 The Contractor may in its sole discretion provide for such rights of use by Research Sites in respect of Contractor Background IP and Foreground IP as it considers appropriate and necessary to achieve the Deliverables and to enable the Contractor to appropriately perform its obligations in relation to the Research and under this Contract (including with respect to the conduct of the relevant Study).

15.9 Any such rights of use referred to in Condition 15.8 shall be provided for in the Deployment Agreement.

15.10 Unless the Authority has given its prior consent in writing (such consent not to be unreasonably withheld or delayed), the Contractor shall not enter into any agreements in which the Intellectual Property arrangements would adversely affect the Contractor's ability to comply with the terms of this Contract.

15.11 The Contractor shall endeavour to ensure, and shall endeavour to ensure that the Collaborator(s) shall endeavour to ensure that a suitable agreement is in place to ensure the effective performance of the Research by Collaborators, Research Sites and sub-contractors in accordance with the terms of this Contract.

16. EXPLOITATION OF INTELLECTUAL PROPERTY

16.1 The Contractor shall inform the Authority in a timely manner of any outcomes from the Research relating to the generation of any Foreground IP or Arising Know How, which the Contractor considers is reasonably likely to be capable of exploitation either by direct adoption into the healthcare service or for the Patient Benefit.

16.2 The Contractor shall develop, implement and maintain procedures for the management of Foreground IP and Arising Know How 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 identification of potentially 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 Foreground IP shall remain vested in the Contractor;

16.2.3 prior to any publication of the Results of the Research, patentable inventions comprised solely and exclusively within the Foreground IP that are identified as patentable by Contractor, are considered by Contractor for patentability (where Contractor considers appropriate and commercially reasonable in the circumstances);

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 (if and as relevant);

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 (if and as relevant); and

16.2.6 any patent applications filed in relation to Foreground IP are diligently prosecuted having regard to all relevant circumstances.

16.3 On the Authority's reasonable request (which may be made once in each twelve (12) month period following the Commencement Date), the Contractor shall provide the Authority with sufficient information as is reasonably necessary to permit the Authority to analyse the operation and effectiveness of the Contractor's procedures for the management of Foreground IP (as such procedures are required by this Contract) 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 (having regard only to expressly relevant requirements of this Contract relating to such dissemination and/or exploitation for the public benefit). If the information provided pursuant to the foregoing is deemed insufficient by the Authority (acting reasonably and in good faith), the Authority (or its authorised representative) may 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. Any information, records or other materials provided or accessed pursuant to or in connection with this Condition 16.3 shall be held by the Authority subject to Condition 9.

16.4 Consistent with the good management of Intellectual Property and subject to the written agreement of the Authority, the Contractor shall use reasonable endeavours to:

16.4.1 where reasonable and practicable and deemed appropriate by the Contractor (in its sole discretion), promote the dissemination of the Foreground IP and Arising Know How in order to achieve Patient Benefit;

16.4.2 where reasonable and practicable and deemed appropriate by the Contractor (in its sole discretion), exploit such Foreground IP and Arising Know How to generate either capital or revenue or both; and

16.4.3 keep proper records showing the description of Foreground IP generated.

16.5 The Contractor shall and shall endeavour to procure that any Collaborator shall provide prior written notification to the Authority before it or any Collaborator, as the case may be, makes any Commercial Use of, or expressly permits any third party to make any Commercial Use of, the Foreground IP. The Contractor shall or shall endeavour to procure that any Collaborator shall provide all appropriate non-confidential details of any proposed commercialisation arrangement that relates solely and exclusively to the proposed Commercial Use of the Foreground IP ("**Proposed Commercial Use Arrangement**"), including but not limited to any non-confidential deal sheet or commercial terms in circulation, which information the Authority shall keep confidential in accordance with Condition 9. The Authority shall within thirty (30) Business Days of such a written notification inform the Contractor and/or Collaborator if the Authority wishes the Contractor and/or Collaborator (as applicable) to enter into a commercialisation agreement with the Authority relating to the exploitation of the Foreground IP that is the subject of, and only for the purposes described in, the Proposed Commercial Use Arrangement – any such commercialisation agreement with the Authority may:

16.5.1 address the distribution of revenue, equity or other benefits arising from the proposed commercialisation arrangements and rights to use the relevant Foreground IP;

16.5.2 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 relevant Foreground IP;

16.5.3 take into consideration the relative contribution of the Authority, the Contractor, the Collaborator(s) and other third party funders or contributors to the relevant Foreground IP; and

16.5.4 where the relevant Foreground IP was generated using datasets provided by a Research Site, take into consideration:

(a) the five principles governing the sharing of patient data: https://www.gov.uk/government/publications/creating-the-right-framework-to-realise-the-benefits-of-health-data/creating-the-right-framework-to-realise-the-benefits-for-patients-and-the-nhs-where-data-underpins-innovation

(b) payment and royalties to NHS Collaborators with NHS Collaborators for the sharing of health and care data; and

(c) advice from NHSX on any commercial arrangements with NHS Collaborators for the sharing of health and care data.

16.6 Unless agreed otherwise in writing, and only where applicable and agreed pursuant to Condition 16.5, the Contractor shall ensure that any proceeds of commercialisation allocated to the Authority as a result of any Commercial Use are distributed according to the terms of the relevant revenue sharing agreement, which may be agreed pursuant to Condition 16.5.

16.7 In the event that the Contractor and/or a Collaborator decides to put certain Foreground IP to Commercial Use under Condition 16.5, without limiting its freedom to operate, then each of the Contractor and/or Collaborator will take due consideration of the Authority's attitude to access to essential health related technologies including medicines in the developing world (if and as relevant).

16.8 .At the cost of the Authority, 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 reasonably require for the purpose of giving the Authority the expressly stated benefit of the provisions of this Contract.

17. PUBLICATION BY CONTRACTOR

17.1 The Contractor shall (and shall procure that each member of its staff engaged on the Research shall) use all reasonable endeavours to comply with the Authority's relevant Guidance on the Publication of Research Outputs (a copy of which is attached as SCHEDULE F to this SECTION 2) – **provided always**

17.1.1 that under no circumstances shall any compliance with this Condition 17.1 and/or SCHEDULE F require the Contractor to publish, disseminate, open source or disclose any Sensitive Material; and

17.1.2 this Condition shall not apply where the Contractor and/or Collaborator has a contractual, legal or similar obligation to publish specific details about the Contract or the Research.

For the avoidance of doubt the obligation described in Condition 17.1 continues after the end of the Research Period.

17.2 The Contractor further acknowledges that a breach of Condition 17.1 by the Contractor may be taken into account by the Authority when considering future applications for Authority funding from the Contractor.

17.3 The Contractor shall comply, and shall ensure that the Collaborator(s) 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 NHS, NHSx and Department of Health and Social Care brands, names and logos.

18. PUBLICATION BY AUTHORITY

18.1 Subject to the provisions of Condition 18.8 and Condition 9 and notwithstanding the provisions of Condition 15, the Authority's Representative may publish the Reports for non-commercial purposes in conjunction with the Authority's statement on Open Access to research "Statement on DHSC funded research and UK 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.

18.2 The Contractor shall assign to the Authority on behalf of the Crown any and all copyright in the Reports 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 only to the copyright in the Report and does not extend to the Intellectual Property or Know How described therein.

18.3 The Authority hereby grants to the Contractor a non-exclusive, worldwide, perpetual, irrevocable, unlimited, royalty-free and transferable licence, with a right to sublicense (through multiple tiers), to freely use the Reports and rights assigned under the assignment referred to in Condition 18.2.

18.4 If and to the extent relevant, the Contractor undertakes to obtain an assignment to the Authority (including through a chain of assignments ultimately ending in the assignment referred to in Condition 18.2) of any copyright in the Reports 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.

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

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

18.6 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".

18.7 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 funded by the NHSX ([PROGRAMME NAME, TITLE AND REFERENCE NUMBER]). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, NHSX or the Department of Health and Social Care."

18.8 Under no circumstances shall the Authority, nor shall the Authority instruct, permit or suffer any other person to, publish, disclose, disseminate, open source any materials, data, content, information or any other thing, which contain any Sensitive Materials – and the Authority hereby fully indemnifies, and agrees to keep indemnified, the Contractor and its licensors, officers, employees and agents from and against any and all liabilities, damages, losses, costs, charges and expenses incurred (either directly or, notwithstanding Condition 23.6, indirectly) as a result of the Authority's breach of this Condition 18.8.

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 on demand 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:

19.3.1 the Contractor is subject to an Insolvency Event;

19.3.2 the Contractor is in material breach of any of the terms and conditions of this Contract, and either:

(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) the breach is not capable of remedy; or

19.3.3 the Contractor commits a Persistent Service Support Default; or

19.3.4 an event of Force Majeure exists for more than six (6) months.

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 9 – 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.

20.2 Upon Termination of this Contract (howsoever occurring and including expiry) any provision of this Contract that expressly or by implication is intended to come into or continue in force on or after termination of this Contract shall remain in full force and effect.

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.

22. FORCE MAJEURE

22.1 In the event that any Party is prevented or 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.

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 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;

23.1.4 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,

23.1.5 the Research (including the Service Support) will be carried out by appropriately experienced, qualified and trained personnel with all due skill, care and diligence;

23.1.6 in carrying out the Research, the Contractor will use all reasonable efforts to ensure that sufficient authorisation has been obtained to permit the use of any Intellectual Property that is reasonably necessary to enable the use of the Foreground IP and Arising Know How to the extent necessary to exercise any rights under, or to perform, this Contract;

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:

23.2.1 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

23.2.2 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.

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 any third party claim made or brought against the Authority relating to:

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,

in and to the limited extent resulting from the act or omission of the Contractor, and, for the avoidance of doubt, excepting in so far as such damage or injury (including infringement) can be demonstrated by the Contractor to be due to any act or neglect of the Authority, or their officers, servants or agents.

23.4 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.

23.5 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 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.

23.6 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.

23.7 Subject to paragraph 23.8, the Contractor's total aggregate liability in contract, tort (including negligence or breach of statutory duty), misrepresentation (whether innocent or negligent), restitution or otherwise, arising in connection with the performance or contemplated performance of this Contract shall under no circumstances exceed £2,000,000.

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

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

23.8.2 fraud or fraudulent misrepresentation.

24. INSURANCE

24.1 Without prejudice to Condition 23.3, 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.

24.2 The Contractor shall produce on demand by the Authority documentary evidence that any insurance policies required by Condition 24.1 are in force.

24.3 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 Condition 23.3.

25. ASSIGNABILITY

25.1 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.

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

25.3 Notwithstanding Condition 25.2, 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 (including any Contractor's Collaboration Agreement between the Contractor and any Collaborator) 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.

26. WAIVER

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 Condition 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 Condition, whether or not the Contract has been terminated.

27.3 In exercising its rights or remedies under this Condition, 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

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

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 The Contractor acknowledges that the Authority is subject to the requirements of the FOIA and the Environmental Information Regulations and shall assist and cooperate with the Authority at the Contractor's expense to enable the Authority to comply with these requirements.

32.2 The Contractor shall and shall procure that its sub-contractors shall:

32.2.1 transfer to the Authority all requests for information that it receives under FOIA and the Environmental Information Regulations ("Requests for Information") that in its opinion are for the Authority consulting the Authority where it has any doubt whether the request is for the Authority as soon as practicable and in any event within two working days of receiving a request for information;

32.2.2 provide the Authority with a copy of all information in its possession, or power in the form that the Authority requires within five working days, or such other period as the Authority may specify, of the Authority's request; and

32.2.3 provide all necessary assistance as reasonably requested by the Authority to enable the Authority to respond to the 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 Subject to provisions of the Code of Practice on Government Information, FOIA or the Environmental Information Regulations, the Authority shall use all reasonable endeavours to ensure that the commercially sensitive information and/or any other Sensitive Material is not disclosed in response to any Request for Information.

32.4 In no event shall the Contractor respond directly to a Request for Information unless expressly authorised to do so by the Authority.

32.5 The Contractor acknowledges that (notwithstanding the provisions of Condition 9) the Authority may, acting in accordance with the former

Department of Constitutional Affairs' Code of Practice on the Discharge of the Functions of Public Authorities under Part 1 of the Freedom of Information Act 2000 ("the **Code**"), be obliged under the FOIA, or the Environmental Information Regulations to disclose information concerning the Contractor or the Research:

32.5.1 in certain circumstances without consulting the Contractor; or

32.5.2 following consultation with the Contractor and having taken their views into account;

provided always that where Condition 32.5.1 applies the Authority shall, in accordance with any recommendations of the Code, take reasonable steps, where appropriate, to give the Contractor advance notice, or failing that, to draw the disclosure to the Contractor's attention after any such disclosure.

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.

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 relating to any individual involved in the Research 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

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

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

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 29 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 08 September 2020 between the Contractor and the Secretary of State for Health and Social Care ("the Contract"), subject always to Condition 18.2 of the Contract, I/We .....Contractor hereby assign all copyright to which I am / we are legally entitled in the Reports (as defined in the Contract) to the Secretary of State for Health and Social Care on behalf of the Crown.

Signed by: ..... [redacted] .....

Date: 11/25/2020 .....

Name in Block Capitals: [redacted] .....

SCHEDULE B VARIATION TO CONTRACT FORM

Project Title :

Project Application No:

Contract between the Secretary of State for Health and Social Care ("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 NOT USED

SCHEDULE D **NOT USED**

SCHEDULE E STATE AID

1. The Contractor agrees that it will not make any change to the structure of funding of the Research as set out in SECTION 4, knowingly or otherwise, which will lead to a breach of State Aid Legislation.
2. The Contractor understands and acknowledges that the funding from the Authority under this Contract may be classed as State Aid.
3. If any payment made under this Contract is considered to be unlawful state aid by the European Court of Justice or any national court of competent jurisdiction and an un-appealable order for its repayment is made, the Contractor will repay the relevant payment within ninety (90) days of demand together with any such interest as may be applicable.

SCHEDULE F AUTHORITY POLICY AND GUIDANCE ON THE PUBLICATION OF RESEARCH OUTPUTS

This guidance outlines NIHR's approach to research outputs from its research funding programmes (UK and global health) and career development programmes (Academy).

The NIHR tracks research outputs from funded research projects and researchers throughout the research and for between 3 and 5 years afterwards. NIHR-funded researchers are expected to publish their main study findings in a peer-reviewed, open access journal.

Five of our research programmes - Efficacy and Mechanism Evaluation (EME), Health Services and Delivery Research (HS&DR), Health Technology Assessment (HTA), Programme Grants for Applied Research (PGfAR) and Public Health Research (PHR) - also require researchers to publish a full account of their research project in the NIHR Journals Library.

Key outcomes and trial protocols are to be made publicly available within 12 months from primary study completion. Clinical trial findings should be published in a peer-reviewed journal within 24 months from study completion. Read more in our policy on clinical trial registration and disclosure of results.

Research outputs should appropriately acknowledge all NIHR funding and support received for the research and include the NIHR disclaimer. Outputs may display the 'Funded by NIHR' logo, where appropriate.

Notifying NIHR of upcoming research outputs

Previously NIHR required 14 or 28 days prior notice (depending on the funding scheme) of publication of research outputs including research papers and media activity. In September 2020 the policy was revised as follows:

- With the exception of all outputs from the Policy Research Programme the NIHR will no longer enforce the 14/28 days prior research output publication notification requirement that was a feature of NIHR research funding contracts signed before September 2020; the requirement will be absent from future contracts.
- Award holders, through their host institution communications teams, will continue to be required to send details of all media activity (e.g. press releases, media exclusive journalist briefings etc) to the relevant NIHR coordinating centre team. This notification should take place as soon as reasonably practicable and a minimum of three working days prior to any journalist outreach, and should include copies of all press releases and, where possible, the relevant research papers.
- NIHR coordinating centres will work with award holders to identify a selection of projects with particularly newsworthy, impactful or sensitive outputs (see below for Assessment Criteria for Prior Notification). For these selected outputs coordinating centres will work with colleagues from across NIHR communications, dissemination, public & patient engagement and policy teams to support the researchers in communicating and disseminating their work. This support will include collaborative proactive planning and distribution of selected press releases through NIHR Communications using NIHR, and sometimes DHSC channels and spokespeople. It will also include flagging research with sensitive outputs to DHSC and their media team.

This means that many NIHR award holders will no longer be required to provide prior notification and final copies of all their research papers or other outputs to the NIHR 14/28 days before they enter the public domain. Instead, award

holders will report their award progress through normal reporting processes including Researchfish. This will ensure the NIHR continues to be able to understand and report on the outputs, outcomes and impact of NIHR funded research.

These changes have been made in response to feedback from award holders. Our intention is to shift the focus from publication risk management to early identification of selected media opportunities and outputs which merit amplified dissemination where NIHR may be able to support the work of host institutions.

The position remains that Policy Research Programme award holders should provide at least 28 days prior notification before the date intended for submission for publication of all types of research outputs, including research papers and all media activity.

Assessment criteria for notification

The following criteria will be used by NIHR coordinating centres in collaboration with award holders to review awards and outputs to identify a selection for which prior notification will be required prior to public disclosure:

- Is the research likely to generate newsworthy and/or potentially impactful outputs? For example:
  - Is it a first? In human/ ever/ in the UK?
  - Is it the biggest study on a certain topic?
  - Does the condition/ health/care issue affect a large number of people or seriously impact the lives of a smaller number of people (e.g. rare diseases)?
  - Is this a topic that is featured heavily in the media or public discourse?
  - Could the results of the research change practice in health, public health or social care?
  - Does the research study under-represented groups or take place in an unusual setting?
  - Are the results surprising or pivotal?
  - Does the research have the potential to make a significant impact on the lives of the public, patients, carers or service users?
  - If implemented, could the research findings deliver significant cost savings or generate economic returns (e.g. through creation of jobs)?

- Is the research likely to generate sensitive outputs? For example:
  - Is the research focusing on areas which are ethically, socially, politically, legally or commercially contentious?
  - Is the research evaluating current policies or approaches?
  - Does the output challenge/ critique current policies or approaches?
  - Do the research findings demonstrate that current treatments/ approaches can cause harm?

Awards will be assessed against these criteria at the outset and periodically through the lifetime of the award.

Notification process

Funding awards selected through the assessment criteria for prior notification, and all Policy Research Programme awards, should be notified to the NIHR. How to submit notification and a copy of your research output varies by research programme. The following table describes how to submit notifications

Programme	Submission process
Efficacy and Mechanism Evaluation (EME) Evidence Synthesis (ES) Health Services and Delivery Research (HS&DR) Health Technology Assessment (HTA) Public Health Research (PHR)	Please submit output notification to the Management Information System (MIS). If you do not have access to the MIS, please email your output notification to us. Please keep us updated about the progress of your output (e.g. from submission to acceptance/rejection or acceptance to publication) by updating the MIS.
Invention for Innovation (i4i) Policy Research Programme (PRP) Programme Grants for Applied Research (PGfAR) Programme Development Grants (PDG) Research for Patient Benefit (RfPB)	Please submit output notification by email directly to the research programme: • Invention for Innovation • Policy Research Programme • Programme Grants for Applied Research • Programme Development Grants • Research for Patient Benefit Please keep us updated by email of the progress of your output.
Global Health Research Unit or Group Global Health Policy and Systems Research (HPSR) Programme	Please login to the MIS. Please keep us updated about the progress of your output (e.g. from submission to acceptance/rejection or acceptance to publication) by updating the MIS or by emailing us.
Research and Innovation for Global Health Transformation (RIGHT) Global Effort on COVID-19 (GECO) programme	Please submit output notification by email to the NIHR Central Commissioning Facility Global Health team.
NIHR Academy funding awards	Please submit output notification by email to the NIHR Academy.

Types of research output

A research output is any item arising from NIHR-funded research that enters the public domain. Outputs can be written, verbally presented, audio/visual or electronic. The NIHR takes a broad definition of what constitutes a research output. Key examples for reporting research findings are shown below.

Research output	Examples
Publications	Books, Book Chapter, Conference Proceedings / Conference Paper, Consultancy Report, Journal Article / Review, Manuals/Guides, Monograph, Policy Briefing Report, Systematic Review, Technical Report or Standard
Engagement activity based outputs	Talk or presentation; Magazine or newsletter (print or online) piece; Media interview, press release, press conference or other response to a media enquiry; Engagement focused website, blog or social media channel; Broadcast e.g. TV/radio/film/podcast.
Influence on Policy, Practice, Patients and the Public	Training for practitioners, Health and care guidelines, Policy documents, Participant materials
Research tools and methods	Biological samples, Cell line, Technology assay or reagent, Model of mechanisms or symptoms, Physiological assessment or outcome measure, Antibody
Research database and models	Database/Collection of data, Data analysis techniques, Computer model/algorithms, Data handling & control
Intellectual property	Patents, trademarks
Medical Products, Interventions and Clinical Trials	Diagnostic Tool, Therapeutic Intervention, Preventative Intervention, Management of Diseases and Conditions, Health and Social Care Service design, Support Tool
Software and technical products	Software, New/Improved Technique/Technology

If you are not sure whether something qualifies as an output, please get in touch with the relevant research programme or Academy funding scheme.

Research papers

Open access policy

The NIHR supports the principle of open access to the outputs of research, which can offer both social and economic benefits, as well as aid the development of new research and stimulate wider economic growth of the UK economy. The NIHR is also committed to adding value in research, one aspect of which is ensuring that research results are published in full in an accessible and unbiased report.

See our open access policy for more information.

NIHR Journals Library

The NIHR is the world's first health research funder to publish comprehensive accounts of its commissioned research within its own publicly and permanently available journal series.

The NIHR Journals Library comprises a suite of five open access peer-reviewed journals reporting results from a range of health research areas.

Studies funded under the following research programmes are required to submit a final report for publication in the relevant NIHR journal:

- Efficacy and Mechanism Evaluation (EME)
- Evidence Synthesis
- Health Services and Delivery Research (HS&DR)
- NIHR Health Technology Assessment (HTA)
- NIHR Programme Grants for Applied Research (PGfAR)
- NIHR Public Health Research (PHR)

Although publication in the NIHR Journals Library meets the requirements of the NIHR open access policy, the NIHR encourages researchers to also publish in other high impact peer-reviewed journals.

More information on submitting your final report is available on the NIHR Journals Library website.

Press releases

Media activity that should be notified to the NIHR includes:

- A press release being issued through the researchers' host or partner institution
- A press release being issued by the journal, funder or partner in the research
- A researcher taking part in interviews for press or broadcast

Please get in touch with the comms team in the relevant NIHR coordinating centre as soon as you and your institution's media team have decided to issue a press release or prepare for media activity. Please supply a copy of the research paper/report, where appropriate.

The coordinating centre will review the press release and share it with the relevant staff at the NIHR and the Department of Health and Social Care (DHSC). All embargoes and confidentiality requirements will be respected by the NIHR and DHSC.

What to include in the body of press releases

Acknowledge the NIHR

Press releases must acknowledge NIHR funding or support for the research by naming and linking to the National Institute for Health Research (NIHR), ideally in the first or second paragraph of the body of the press release.

Examples:

- Researchers funded by the National Institute for Health Research (NIHR)

- Research funded by the National Institute for Health Research (NIHR)
- Researchers at the University of Bristol funded by the National Institute for Health Research (NIHR)
- NIHR research(ers) at the University of Leeds...'
- An NIHR study at ....

What to include in the 'Notes to Editors'
Add our boilerplate

Please include the following NIHR boilerplate in the notes to editors section of your press release:

STARTS

The National Institute for Health Research (NIHR) is the nation's largest funder of health and care research. The NIHR:

- Funds, supports and delivers high quality research that benefits the NHS, public health and social care
- Engages and involves patients, carers and the public in order to improve the reach, quality and impact of research
- Attracts, trains and supports the best researchers to tackle the complex health and care challenges of the future
- Invests in world-class infrastructure and a skilled delivery workforce to translate discoveries into improved treatments and services
- Partners with other public funders, charities and industry to maximise the value of research to patients and the economy

The NIHR was established in 2006 to improve the health and wealth of the nation through research, and is funded by the Department of Health and Social Care. In addition to its national role, the NIHR supports applied health research for the direct and primary benefit of people in low- and middle-income countries, using UK aid from the UK government.

ENDS

You may also wish to include in the notes to editors additional information about the specific NIHR programme or training scheme that the press release relates to.

Acknowledge the role of patient data

The NIHR recognises and values the role of patient data, both in underpinning and leading to improvements in research and care.

Examples of types of patient data used in research include:

- GP records
- Clinical audits, for example the National Diabetes Audit
- Disease registers, such as the National Cancer Registration and Analysis Service
- Hospital Episode Statistics
- Diagnostic imaging datasets
- Prescribing databases
- Patient surveys, for example Patient Reported Outcome Measures (PROMs)
- Information collected during clinical trials and cohort studies
- Data in large patient cohorts, such as the NIHR BioResource and the UK Biobank

We ask researchers who use patient data to acknowledge it by incorporating a data citation, developed by use MY data, in publications and stories that would not have been possible without access to this data. This expectation also extends to press releases on such research.

Please use the following patient data citation after the NIHR boilerplate in press releases:

STARTS

This work uses data provided by patients and collected by the NHS as part of their care and support and would not have been possible without access to this data. The NIHR recognises and values the role of patient data, securely accessed and stored, both in underpinning and leading to improvements in research and care. www.nihr.ac.uk/patientdata

ENDS

Please use this citation in all press releases, unless you feel that the research does not use patient data in any form.

Use of the NIHR logo

The NIHR logo (including Funded/Supported by NIHR logos) should not be used in press releases issued by a researcher, research team, or private company. Such press releases should use the researchers' host institution's logotype.

Only press releases issued by the NIHR's Press Office or an NIHR Coordinating Centre may use the NIHR logo.

Acknowledging the NIHR in research outputs

All written and oral research outputs should acknowledge the NIHR funding in full and include the NIHR disclaimer. For research papers, the acknowledgement and disclaimer should be added to the funding or acknowledgments section of the manuscript. Where possible the unique NIHR project reference number should be included. Acknowledgement of NIHR greatly aids the automated identification of research outputs and contributes to NIHR's ability to report accurately on the outputs, outcomes and impact of the work we fund.

Please acknowledge all types of NIHR funding, support and affiliations, such as:

- research programme funding
- whole or part funding or support by research centres or units
- use of clinical research facilities, centres or units
- fellowship awards
- professional training awards
- Senior Investigator awards
- Research Professorship awards.

Studies supported by the Clinical Research Network should be encouraged to acknowledge the support provided by the Network.

Please note that although the Department of Health and Social Care funds the NIHR, the Department should not be named as the funder. The NIHR should be accredited as the funder.

Chief investigators/lead researchers should refer to their funding contract to ensure that they comply with the specific terms and conditions regarding naming and acknowledging the NIHR appropriately in research publications.

It is helpful if outputs, where possible, have a DOI and metadata is deposited in an appropriate database.

Wording for researchers funded by NIHR research programmes

Please use the project reference number when acknowledging NIHR funding in research outputs. Use of the correct project reference greatly aids the automated identification of publications and contributes to NIHR's ability to report accurately on the outputs, outcomes and impact of the work we fund.

All research programmes (except EME)

This study/project is funded by the National Institute for Health Research (NIHR) [name of NIHR programme (project reference xxx)/name of part of the NIHR]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

EME programme

This project (project reference xxx) is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership. The views expressed in this publication are those of the author(s) and not necessarily those of the MRC, NIHR or the Department of Health and Social Care.

Wording for researchers funded by the NIHR Global Health Research programme

This research was funded by the National Institute for Health Research (NIHR) (project reference xxx) using UK aid from the UK Government to support global health research. The views expressed in this publication are those of the author(s) and not necessarily those of the NIHR or the UK Department of Health and Social Care.

Wording for researchers who hold training or career development funding awards (except the Integrated Clinical Academic (ICA) Programme)

(Name of the researcher) is funded by a National Institute for Health Research (NIHR) (Award name e.g. Doctoral Research Fellow) for this research project.Wording for researchers who hold ICA training or career development funding awards

(Name of the researcher) is funded by a Health Education England (HEE)/National Institute for Health Research (NIHR) (Award name e.g. Clinical Doctoral Fellow) award for this research project.

Branding research outputs

The ‘Funded by the NIHR’ logo (see below) is available for use on research outputs funded by an:

- NIHR research programme
- NIHR Academy programme

We encourage you to use the 'Funded by NIHR' logo on visual and digital outputs, such as research posters, research slides and websites (but not in original research papers or your host institution's press release about your research). It should be positioned along with an acknowledgment and a disclaimer as follows:

- On websites above the fold but not in the header i.e. so that it is visible without scrolling down the page
- In print, such as on your institution's templates for research posters and patient leaflets, below the fold/in the bottom half of the page
- In research slides, use the ‘Funded by NIHR’ logo on the first slide and the appropriate acknowledgement and disclaimer on the final slide.

For research posters, as an alternative you can use an NIHR poster template, to which you can add your host institution logo.

Should your research study have its own logo, this can also be used on outputs, providing the NIHR acknowledgement is also in place.

If your project is part of the MRC Clinical Trials portfolio, special arrangements apply (please contact EME to find out more).

Part AUsing the 'Funded by NIHR' logo

Download the 'Funded by NIHR' logo to use on your research outputs.

Funded by NIHR logo - colour

FUNDED BY

NIHR | National Institute for Health Research

CMYK PNG file
CMYK EPS file
RGB JPG file
RGB EPS file
RGB SVG file

Funded by NIHR logo - black

CMYK PNG file
CMYK EPS file
RGB JPG file
RGB EPS file
RGB SVG file

Funded by NIHR logo - white

CMYK PNG file
CMYK EPS file
RGB EPS file
RGB SVG file

Researchers funded by the NIHR Global Health programme

Projects funded by the Global Health Research programme should refer to the Global Health identity guidelines.

SECTION 3 RESEARCH

This contents of Part A and Part B of this SECTION 3 set out the Parties' provisional intentions with respect the nature and scope of the Research and associated Deliverables, the Studies and associated Research, and prospective Collaborators and Research Sites. However, it is expressly noted and agreed that the Parties intend to enter into Variation (as described in Part D of this SECTION 3), which shall detail in fuller and more specific details the nature of and scope of the Research and the Parties' respective obligations in relation thereto.

Part B: Research and Collaborators

1. Research:

Three distinct real world testing studies and the 'deployment' of Mia™ in fifteen (15) breast screening units (each being a "**Research Site**") throughout England over the Research Period in accordance with the provisional timeline detailed in Part B of this SECTION 3.

Prior to starting the first Study – it is acknowledged that Mia™ needs to connect to a test instance of the NHS Breast Screening System operated as part of the NHS Breast Screening Programme, which is led by Public Health England. The Authority shall use all reasonable efforts to ensure that the Contractor is able to effect such connection, including:

- procuring all necessary or desirable technical information, manuals and guides relating to the operation and configuration of NHS Breast Screening System (including installation and servicing document, ODBC connection/installation documentation etc); and
- procuring necessary steps and measures be taken by third parties upon whom a dependency exists (including Public Health England and Hitachi).

2. Studies:

- Study 1 – Large-scale phase II retrospective and reader study
- Study 2 – Real-world (prospective) validation, cost effectiveness evaluation, and extended generalisability analysis.
- Study 3 – Comprehensive post-market validation for national roll-out

3. Collaborator:

The Research involves trial collaboration with Alan Turing Institute on research for assessment method development and independent monitoring of robustness.

4. Research Sites:

Year 1 Research Sites

1. North Bristol NHS Trust
2. Breast Test Wales (Central PACS)
3. North London Breast Screening Service
4. Newcastle upon Tyne Hospitals NHSFT
5. Royal Devon and Exeter NHSFT (via In Health Group)

Year 2 Research Sites

Five further Research Sites to be agreed between the Parties (including by way of the Variation noted in Part D of this SECTION 3).

Year 3 Research Sites

Five further Research Sites to be agreed between the Parties (including by way of the Variation noted in Part D of this SECTION 3).

Part C: Deliverables

1. Agreement of Evaluation scope (31 January 2021)
2. Deployment Agreements signed with Year 1 Research Sites (31 March 2021)
3. 1-year Patient Impact and Cost Effectiveness Report from post-market surveillance (30 June 2021)
4. First five offline deployments (i.e., Mia™ is operating in 'shadow mode' – as that term or an equivalent concept is defined or described in the relevant Deployment Agreement) at Year 1 Research Sites completed in accordance with the relevant Deployment Agreements (30 September 2021)
5. First Patient and Public Involvement Report (30 September 2021)
6. Completion of an initial retrospective trial (31 October 2021)
7. Completion of Study 1 (31 December 2021)
8. Second five offline deployments (i.e., Mia™ is operating in 'shadow mode' – as that term or an equivalent concept is defined or described in the relevant Deployment Agreement) at Year 2 Research Sites completed in accordance with the relevant Deployment Agreements (30 September 2022)
9. Second Patient and Public Involvement Report (30 September 2022)
10. Mia™ is live (i.e., Mia™ is being deployed and used as an 'independent reader' – as that term or an equivalent concept is defined or described in the relevant Deployment Agreement) at a minimum of five Research Sites (31 December 2022)
11. Post-market Surveillance Report (31 March 2023)
12. Final five offline deployments (i.e., Mia™ is operating in 'shadow mode' – as that term or an equivalent concept is defined or described in the relevant Deployment Agreement) at Year 3 Research Sites completed in accordance with the relevant Deployment Agreements (30 June 2023).

Part D: Service Support and Continuity

The Contractor shall:

- maintain throughout the Research Period a Business Continuity and Disaster Recovery plan; and
- use reasonable efforts to procure, and maintain throughout the Research Period, that Mia™ is certified as ISO 27001 compliant.

The Contractor shall ensure that the Deployment Agreement shall (with effect from 'going live' (as that term or any analogous concept is defined in the Deployment Agreement)) provide for 'service levels' and 'support services' (which shall include provisions to address concepts such as 'service level failures', and 'persistent service level failures'), which are of a standard that is no worse than common industry standards and practices, having regard to the nature of the service provided under the Deployment Agreement (including the manner of deployment – e.g., an 'on-premise' of 'Software-as-a-Service' based deployment).

As part of the Collaboration described in Part D of this of this SECTION 3, the Parties shall agree a definition of a "**Persistent Service Support Default**" for the purposes of Condition 1.1 of SECTION 2, which shall:

- be defined with reference to;
- but shall under no circumstances be more onerous or punitive on or to the Contractor than,

the provisions of the Contractor's proposed commitments to Research Sites in relation to the definition of 'service level failures', and 'persistent service level failures' (or similar or analogous concepts) under the Contractor's pro-forma Deployment Agreement.

Part E: Collaboration

Promptly following the Commencement Date, the Parties shall work together in good faith and use all reasonable endeavours to prepare and execute a Variation to this SECTION 3, which will permit this SECTION to more particularly and completely describe:

- the scope and nature of the Research;
- in a level of technical and practical detail and granularity commensurate with the nature of the Research and the amount of the Approved Cost – details of the Deliverables and the Studies and associated Research (including, what it shall mean for a deployment of Mia™ to be 'live' and 'competed' for the purposes of the Deliverables noted above);
- the definition of a Persistent Service Support Default (as referred to in Part C of this this SECTION 3);
- details of the proposed Collaboration with the Alan Turing Institute;
- the technical requirements and definition of the 'connection' of Mia™ with the NHS Breast Screening System; and
- any third party dependencies identified by the Parties', and allocation of responsibility as between the Parties in respect who is responsible for ensuring that such dependencies are met in manner that allows the relevant Party's(ies') effective performance of the Research and this Contract.

Each Party shall ensure that appropriately senior, experienced, qualified and trained personnel and advisers (e.g., legal counsel) participate in the collaboration described in this Part D to SECTION 3 and attend (virtually or in-person) such meetings as are reasonably required for the purpose.

Any and all references to the Research, the Research, the Studies and otherwise to this SECTION 3 in this Contract shall be considered in light of the provisional nature of the

specifics detailed in this SECTION 3 and the proposed Variation hereto described in this Part D.

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.

Date	**Amount (£)**
1. 30 November 2020	[redacted]
2. 31 March 2021	[redacted]
Financial Year 2021/22 sub-total	
3. 30 June 2021	[redacted]
4. 30 September 2021	[redacted]
5. 31 December 2021	[redacted]
6. 31 March 2022	[redacted]
Financial Year 2022/23 sub-total	
7. 30 June 2022	[redacted]
8. 30 September 2022	[redacted]
9. 31 December 2022	[redacted]
10. 31 March 2023	[redacted]

Financial Year 2023/24 sub-total	
11. 30 June 2023	[redacted]
12. 30 September 2023	[redacted]
Patent Costs	0
TOTAL (to not exceed £15.0m)	15,000,000

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

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.

SECTION 5 **KEY STAFF**

The Contractor's Representative name and address

Name: [redacted]

Address: 147 Eagle Point, 163 City Road, City of London, EC1V 1AT, United Kingdom

The Authority's Representative for contract management purposes

Name: [redacted] AI Strategic Sourcing Lead, NHSX

Address: Skipton House, 80 London Road, London SE1 6LH

The Authority's Representative for project management purposes

Name: [redacted] Innovation Senior Manager, NHS England

Address: Skipton House, 80 London Road, London SE1 6LH

SECTION 6 REPORTING SCHEDULE

The feedback required under Condition 13.4 shall be obtained by or on behalf of the Contractor using the following methods:

1. Formal Quarterly contract review meetings
2. Quarterly reporting returns (which, for the avoidance of doubt, shall not constitute Reports for the purposes of this Contract)

The feedback required under Condition 13.4 shall address the following issues:

1. Key progress updates
2. Risks to the agreed project and evaluation plan
3. Mitigations for these risks
4. Updates on the emerging evaluation evidence base

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

Report	Due date
Interim Report	Within eighteen months of the Commencement Date