RESEARCH CONTRACT

BETWEEN

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE (1)

AND

IRHYTHM 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

IRHYTHM TECHNOLOGIES LTD, a company incorporated in England with company number 10055682 and its principal place of business at Seal House, 56 London Rd, Bagshot GU19 5HL ("**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 AI Award 1897 in accordance with the work specified in SECTION 3 and including the Deliverables and Service Support elements (as defined in SECTION 2 and detailed in SECTION 3), being project application 1897 dated September 8 2020 (the "**Research**").
2. The Authority will pay the Contractor the Approved Cost 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 made pursuant to Conditions 13 and 14 of SECTION 2.
3. This Form of Contract (SECTION 1) together with the attached SECTION 2 to 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.

SIGNED:

For the Authority:

SIGNATURE…… [redacted] …

FULL NAME…… [redacted]

POSITION HELD…… Director of Policy & Strategy, NHSX

ON BEHALF OF THE AUTHORITY

DATE…… 11/19/2020

For the Contractor:

SIGNATUR [redacted] ……

FULL NAME… [redacted] ……

POSITION HELD…… Chief Financial Officer ……

ON BEHALF OF THE CONTRACTOR

DATE…… 11/18/2020 ……

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 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.
"AI Technologies"	means deep learning, machine learning and other artificial intelligence technologies, including but not limited to (a) proprietary algorithms, software that use or deploy neural networks, statistical learning algorithms or reinforcement learning; (b) or proprietary embodied artificial intelligence and related hardware or technologies.
"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 any of the Contractor or any Collaborator or Research Site in the course of the performance of the Research. Notwithstanding the foregoing, Arising Know How excludes any Contractor Background IP, Foreground IP, Third Party IP and Excluded Property.
"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 from The Authority addressed to the Contractor.

"Background IP"	means any Intellectual Property in existence at the Commencement Date or created, devised, generated or developed other than in the performance of the Research and which is actually used in the performance of the Research.
“Business Day”	means a day other than Saturday, Sunday and bank holidays in London.
“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 subject to Condition 15.7 and that is listed at SECTION 3, Part A (ii).
"Commencement Date"	Means September 8, 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 basis; (c) any use in support of the development, promotion or provision of Health Care direct to an individual on a fee paying basis; (d) the provision of a product or a service to any Health Service Body or to any patient under the care of a Health Service Body.
"Completion Date"	means September 8, 2020.
“Confidential Information”	means information of any form, however conveyed and irrespective of the media on which it is stored, that is:

(a) information which has been designated as confidential by either Party; or

(b) information that reasonably ought to be considered as confidential including information which relates to the business, affairs, properties, assets, trading practices, goods/services, developments, trade secrets, Intellectual Property, know-how, personnel, customers and suppliers and commercial sensitive information of either Party; or

(c) Personal Data and/or special category data within the meaning of the Data Protection Legislation.

Confidential Information shall include:

(a) a Party's or Third Party's Background IP; or

(b) Third Party IP; or

(c) Foreground IP;

(d) Excluded Property; or

(e) 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 AND FORM OF REPORTS

"Contractor Background IP" means any Background IP or Know How:

(a) owned by the Contractor or to which the Contractor has rights; and/or

(b) created, devised, generated or developed by or on behalf of the Contractor (including by the Contractor's employees, consultants, agents, and sub-

	contractors),whether solely or jointly, other than in the course of the performance of the Research.
	and in each case which is used in the performance of the Research. Notwithstanding the foregoing, Contractor Background IP excludes Excluded Property, the Contractor's or a Contractor Affiliates' rights in any Foreground IP, Arising Know How and Third Party IP.
“Contractor’s Collaboration Agreement”	means the agreement(s) between the Contractor and any Collaborator or Research Site who are delivering any part 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, including the Data Protection Act 2018 and, to the extent it forms part of the law in the United Kingdom, the General Data Protection Regulation (Regulation EU) 2016/679).
“Deliverables”	means those elements of the Research detailed in SECTION 3, Part B(i) or otherwise agreed between the Collaborator and the Evaluator.
"Drop Dead Date"	means March 8 2021 the last date by which work on doing the Research must have started.
"Evaluator"	means an evaluator appointed by NHS England pursuant to AI Award 1897.
"Excluded Property"	means any and all (a) iRhythm Products; (b) iRhythm Improved Products; (b) Zio

	Technology; (c) iRhythm Improvements; and (e) Intellectual Property in or arising from or used to develop the aforesaid (including any iRhythm Improvement Know How).
"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, devised, generated or developed (whether in whole or in part) during the course and for the purpose of the Research. Foreground IP: (a) includes Intellectual Property created, devised, generated or developed by or on behalf of the Contractor or any Collaborator in the course of performing the Research; but (b) excludes Arising Know How, Background IP, Excluded Property and Research Data.
"Fraud"	means any offence under laws creating offences in respect of fraudulent acts or at common law in respect of fraudulent acts in relation to the Contract or defrauding or attempting to defraud or conspiring to defraud the Crown.
"Good Industry Practice"	means standards, practices, methods and procedures conforming to the law and the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged in a similar type of undertaking under the same or similar circumstances.
"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 creditor to 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;

(f) ceases or threatens to cease to carry on business;

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

(h) 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, domain names, rights in get-up, goodwill and the right to sue for passing off or unfair competition, rights in designs, database rights, rights in confidential information (including rights in know how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply and be granted) for, and renewals or extensions of, rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.
"Key Staff"	means the persons named in SECTION 5.
"Know How"	has the meaning given to it in Commission Regulation (EU) 316/2014 of 21 March 2014 at Article 1, 1(i).
"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; or (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
"Personal Data"	has the meaning ascribed to it in the Data Protection Legislation.
“Reports”	means any report, executive summary, paper, abstract or other document provided by the Contractor under this Contract pursuant to Conditions 13 and 14 and SECTION 6 (excluding any iRhythm Reports). Reports exclude any and all Excluded Property, Arising Know How, Research Data, Foreground IP or other Intellectual Property described therein.
"Research"	means the scope of work specified in SECTION 3 and includes any Deliverables or Service Support element specified in SECTION 3, Parts B and C.
“Research Data”	means the key outcome measures set out in SECTION 3, Part A(iv) (or otherwise agreed by the Collaborator and the Evaluator) which are not Personal Data that is collected or generated in the performance of the Research. For the avoidance of doubt, Research Data does not include information or data that has been analysed.
"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 in writing unless otherwise determined in

	accordance with the terms of the Contract.
“Research Site”	means any NHS Trust site at which the Research will be performed.
“Service Support”	means any services outlined in SECTION 3 that are to be provided by or on behalf to the Contractor to support the performance of the Research. For the avoidance of doubt, Service Support includes such services provided on behalf of the Contractor by iRhythm Technologies, inc.
“State Aid Legislation”	means any and all legislation of the United Kingdom and the European Union (for so long as it is directly applicable) regarding the provision of state aid.
"Third Party IP"	means any Intellectual Property which is owned or controlled by any party (including any Collaborator) other than the Contractor and over which the Contractor has licensed to use in the performance of the Research or to perform the provisions of this Contract.
"Variation"	means a variation to this Contract agreed and executed in accordance with Condition 6.
"Zio Device"	Zio® XT monitoring devices.
"Zio Technology"	means all computer programmes, software, algorithms, software implementations of algorithms, AI Technologies, models and methodologies, hardware, or other technologies used in or used to develop the Zio Device, Zio Service or any other iRhythm Product.
"Zio Report"	has the meaning given to it in SECTION 3, Part A (i).
"Zio Service"	has the meaning given to it in SECTION 3, Part A (i).
Zio Service Report	has the meaning given to it in SECTION 3, Part A (i).

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

1.2.1 a reference to any statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the statute, enactment, order, regulation or instrument as subsequently amended or re-enacted;

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

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

1.2.4 references to a Party shall include that Party's personal representatives, successors or permitted assignees;

1.2.5 general words are not to be given a restrictive meaning because they are followed by particular examples, and any words introduced by the terms "including", "include", "in particular" or any similar expression will be construed as illustrative and the words following any of those terms will not limit the sense of the words preceding those terms; and

1.2.6 the headings in this Contract are for convenience only and shall not affect its interpretation.

2. COMMENCEMENT AND DURATION

2.1 This Contract shall commence on the Commencement Date and, subject to Condition 2.2 or to earlier termination in accordance with its terms, shall continue in full force and effect until the Completion Date.

2.2 If in the Authority's reasonable opinion, the Research has not effectively commenced by the Drop Dead Date or by such other date as the Parties may agree in writing, the Authority may withdraw the Award and/or any offer of funding and this Contract will terminate.

3. ADMINISTRATION, PERFORMANCE AND DIRECTION OF RESEARCH

3.1 Research commissioned by the Authority is open and, subject to the provisions of this Contract, details of Research are normally published. For the avoidance of doubt the Authority may publish any details of the Research in accordance with the terms of this Contract. Publication of the Research by the Authority will be subject to this Condition 3, Condition 8, Condition 9 and Condition 17.

3.2 The Authority may publish details of the non-confidential research plan and project costs.

3.3 The Contractor shall ensure that each member of staff engaged on the Research undertakes to observe the Conditions of this Contract and any further or supplementary Contract as may be entered into between the Parties

relating to the Research 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 ensure full communication takes place between the Parties and such others as may be notified to the Contractor by the Authority and the Contractor shall advise the Authority as required on the Research. In particular the Contractor must notify the Authority and, if applicable, the relevant research ethics committee of any proposed deviation from the research purpose or if significant developments occur as a study progresses, including developments in relation to the safety of individuals or to scientific direction.

3.6 The Parties acknowledge and agree that the Research involves a Collaborator and/or Research Site and the Contractor shall put a place a Contractor's Collaboration Agreement. Such Contractor's Collaboration Agreement shall be subject to the Authority's prior written consent (such consent not to be unreasonably withheld, delayed or conditioned). The Contractor's Collaboration Agreement shall be submitted to the Authority's Representative within a timetable to be agreed with the Contractor. The Contractor shall not be liable for any delay that may be caused in negotiating and agreeing the terms of the Contractor's Collaboration Agreement (or seeking the Authority's consent) that arise from the relevant Collaborator's or Research Site's readiness to participate in the Research.

3.7 Where the Research involves a Research Site (including where the Research Site is also a Collaborator) the Contractor shall comply with and adhere to any reasonable compliance, governance or security standards, procedures or protocols required by the relevant Research Site (as applicable) and provided to the Contractor in writing.

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

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

4. ACCOUNTING AND PAYMENTS

4.1 Payments will be made by the Authority during the Research Period in accordance with dates and amounts specified in SECTION 4. The Authority may suspend its payment of amounts due under this payment schedule at any time if in the view of the Authority:

4.1.1 reasonable progress on the Research has not been maintained; or

4.1.2 any element of the Service Support or any Deliverable has not been provided in accordance with the detail and timeline set out in SECTION 3; or

4.1.3 reports have not been submitted as required under Condition 13; or

4.1.4 the Contractor has substantially failed to comply with the terms of this Contract (including where the Contractor has failed to procure that any of the Collaborators or Research Sites comply with certain obligations as required by this Contract).

Subject to these limits the Contractor is free to administer the funds within the terms of this Contract without further reference to the Authority.

4.2 The total amount to be paid by the Authority to the Contractor in any financial year shall not exceed the relevant amount detailed in SECTION 4 unless the Authority instructs the Authority's Representative to apply a compounded annual inflationary uplift. The Authority shall apply uplifts only after obtaining approval from finance and treasury. For illustration if the inflationary uplift in year 2 is set at 3% and year 3 at 1%, year 2 fees would be increased by 1.03 and year 3 by 1.03 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.

4.3 The Contractor is responsible for payments to third parties involved with the Research and shall ensure that such payments are made promptly.

4.4 Subject to Condition 4.1, the Authority reserves the right to recover from the Contractor any sum of money allocated in a specific financial year but not actually spent by the financial year ending 31st March. Where reasonably possible such recovery will be by way of set off against future payments. In the event of the Authority exercising its right under this Condition 4.4, a new payment schedule will be issued with the Approved Cost adjusted accordingly.

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 The Contractor shall not make any change in the total remuneration, conditions of service or numbers of staff engaged on the Research which will require a change in the total amount payable, or make material changes to the Research detailed in SECTION 3, without prior written approval being given by the Authority.

4.7 The Contractor grants to the Authority and to any statutory or regulatory auditors of the Authority and to its or their authorised agents the right of reasonable access to (and if necessary to copy) the relevant financial records and/or other information relating to the financial records evidencing use of the amounts paid in accordance with SECTION 4 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, subject to Parties agreeing suitable confidentiality arrangements. Such financial records shall be the Contractor's Confidential Information.

4.8 Subject to the Parties agreeing to terms to safeguard the confidentiality of the Contractor's or a third party's Confidential Information, the Contractor shall provide all reasonable cooperation and assistance at all times during the

currency of this Contract and for a period of six (6) years after termination or expiry of this Contract for the purposes of allowing the Authority to obtain such information as is necessary to fulfil the Authority's obligations to supply information for Parliamentary, Governmental, Judicial or other regulatory or administrative purposes and/or to carry out an audit of the Contractor's compliance with this Contract including all activities, performance, security and integrity in connection therewith.

4.9 Subject to Condition 4.1, on completion of the Research Period, the final payment in respect of costs properly incurred under this Contract will be paid by the Authority to the Contractor within thirty (30) calendar days of all of the following objectives being satisfied:

4.9.1 the Research has been completed to the satisfaction of the Authority;

4.9.2 the reports required under Conditions 13 and 14 have been submitted by the Contractor to the Authority;

4.10 Subject to Condition 4.1, 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 Subject to any dispute existing between the Parties, the Authority shall be under no obligation to make any payment relating to demands for payment under this Condition 4 if such demands are received more than TWELVE (12) months after the completion of the Research Period unless an extension has been requested and agreed in writing.

4.12 If the Contractor disputes the Authority's suspension or withholding of payment of amounts under this Condition 4, the Contractor shall promptly notify the Authority in writing and the dispute shall be resolved in accordance with Condition 29.

4.13 The Contractor is subject to the additional clauses set out in SCHEDULE E: STATE AID.

5. SET OFF

5.1 If any sum of money shall be due from the Contractor to the Authority or any other Government Department, the same may be deducted from any sum then due or which at any time thereafter may become due to the Contractor under this Contract or under any other agreement with the Authority or with any other department, office or agency of the Crown.

5.2 If the Contractor disputes the Authority's deduction of any sums under this Condition 5, the Contractor shall promptly notify the Authority in writing and the dispute shall be resolved in accordance with Condition 29.

6. VARIATION

6.1 If at any time it appears likely that any provision of the Contract, in particular the Research, needs to be varied the Contractor shall immediately inform the Authority in writing requesting a Variation to the Contract, giving full details of the justification for the request and giving proposals for the Variation to the Contract. Upon receipt of such a request the Authority may:

6.1.1 agree to vary the Contract;

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

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

6.1.4 give notice of termination in accordance with Condition 19.

6.2 Any variation to the Contract shall be set out in a Variation to Contract Form as set out at SCHEDULE B to this SECTION 2 and signed by both Parties.

7. STAFF APPOINTMENTS

7.1 The Contractor agrees to use sufficient appropriately skilled resources to enable it to comply with its obligations under this Contract.

7.2 All Contractor's staff providing services in connection with this Contract shall be bound by the same terms and conditions of service which are normally applicable to the Contractor's staff.

7.3 Not used.

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 its staff providing services in connection with this Contract and Collaborators and Research Sites and sub-contractors shall at all times:

7.4.1 observe professional standards; and

7.4.2 where relevant keep scientific notebooks recording all research, development and other work carried out in respect of the Research and the results of such research, development and other work, including keeping bound note books with page numbering recording all results and observations signed by the persons obtaining such results or making such observations, and countersigned appropriately.

7.5 The Contractor shall upon reasonable written request make available to the Authority copies of all records generated in connection with the Research, including for the avoidance of doubt, records generated by its staff or Collaborators or sub-contractors under Condition 7.4 and by any third parties working on the Research. .

8. PUBLICITY

8.1 The Contractor shall (and shall procure that each member of staff engaged on the Research shall) comply with the Authority's reasonable guidance on the publication of research outputs which may be issued by the Authority from time to time. This condition shall not apply where (a) the Contractor and/or a Collaborator has a contractual, legal or similar obligation to publish specific details about the Contract or the Research; or (b) the guidance requires the publication of Confidential Information.

8.2 In the event that the Contractor fails to comply with Condition 8.1 the Authority may:

8.2.1 deem this to be a material breach and terminate this Contract in accordance with Condition 19.4 herein; and/or

8.2.2 suspend or reduce its payment of amounts due under the payment schedule in SECTION 4 of the Contract; and/or

8.2.3 require repayment of all or part of the funding provided under this Contract.

The Contractor further acknowledges that a breach of Condition 8.1 by the Contractor may be taken into account by the Authority when considering future applications for Authority funding from the Contractor.

9. CONFIDENTIALITY

9.1 In respect of any Confidential Information it may receive from the other Party (whether before or after the Effective Date) 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 (provided the aforesaid is not Confidential Information of the disclosing Party or any third party); and

9.1.2 nothing herein shall be so construed as to prevent either Party from using data processing techniques, ideas, know-how and the like gained during the performance of this Contract in the furtherance of its normal business, to the extent that this does not result in a disclosure of any Confidential Information or infringement of any valid Intellectual Property rights of either Party or the unauthorised processing of any Personal Data. For the avoidance of doubt, the aforesaid shall not permit the Authority to use any Contractor Confidential Information, Contractor Background IP, Excluded Property, Third Party IP or Foreground IP.

9.2 The Contractor Background IP, iRhythm Improvements, iRhythm Improvement Know How and Zio Technology and any other Excluded Property are not public knowledge shall be deemed to be the Confidential Information of the Contractor and/or the Contractor's Affiliates (as appropriate). Arising Know How, Research Data and Foreground IP shall be the Contractor's Confidential Information (unless the Contractor has agreed that the aforesaid shall be jointly owned by a Collaborator or Research Site pursuant to a Collaborator Agreement).

9.3 Condition 9.1 shall not restrict a Party from using its own Intellectual Property Rights or Confidential Information.

9.4 Condition 9.1 shall not apply to any Confidential Information received by one Party from the other:

9.4.1 which is or becomes public knowledge (otherwise than by breach of the receiving Party);

9.4.2 which was lawfully in the possession of the receiving Party, without restriction as to its disclosure, before receiving it from the disclosing Party;

9.4.3 which is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure;

9.4.4 is independently developed without access to the Confidential Information; or

9.4.5 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).

9.5 If disclosure is required under Condition 9.1.2, the receiving Party shall (if permitted to do so by law) give the disclosing Party reasonable advance notice of the intended disclosure and a reasonable opportunity to challenge such disclosure. If advance notice is not permitted, the receiving Party shall take reasonable steps to safeguard the confidentiality of the Confidential Information.

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

9.7 If either Party becomes aware or has knowledge of any unauthorised use or disclosure of the disclosing Party's Confidential Information, it shall promptly notify the disclosing Party of such unauthorised use or disclosure. In the event, there is an unauthorised disclosure of the Collaborator's Affiliates' Confidential Information, the Authority shall promptly notify the Collaborator.

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, and will use all reasonable endeavours to ensure that each Collaborator and any Research Site will comply 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;

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

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

Confidentiality and security

10.4 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.

10.5 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.

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

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

10.6.2 the NHS Digital “Code of practice on confidential information”, as amended from time to time.

10.7 In performing the Research, the Contractor shall, and shall ensure that any Collaborator or Research Site, adhere to the following:

10.7.1 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);

10.7.2 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);

10.7.3 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);

10.7.4 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).

10.8 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 sub-contractors, employees, agents or person within its control.

10.9 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 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.

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

11. RIGHTS TO RESEARCH DATA

11.1 Subject to the provisions of Conditions 9, 10 11.3 and 11.4 in the event that in the Authority's reasonable opinion the Research Data is not being appropriately managed, disseminated or used, the Authority reserves the right to have access to and to use the Research Data compiled during the course of the Research, and will respect existing confidentiality obligations in respect of any Research Data which it obtains, and to permit any Health Service Body to access and use the Research Data in order to: (i) support the development, promotion or provision of Health Care; or, (ii) for any other purpose that is not a Commercial Use. The aforesaid rights shall not apply to any Research Data that incorporates Contractor Background IP, Excluded Property, Foreground IP or Third Party IP.

11.2 The Authority shall not be entitled to access, inspect, take or be supplied with or use copies of the Research Data other than in an anonymised form.

11.3 The Authority's right to access and use the Research Data under Condition 11.1 shall be subject to the following:

11.3.1 the Authority providing the Contractor with [30] Business Days' written notice of its intention to access and use the Research Data,

providing details setting out reasons for the access and the proposed use;

11.3.2 the Contractor shall within [30] Business Days provide notice to the Authority confirming whether it agrees or objects to the Authority's use of the Research Data; and

11.3.3 any dispute between the Parties shall be managed and resolved in accordance with Condition 29.

11.4 To the extent that a Collaborator and/or Research Site provides Personal Data regarding a patient to the Contractor, the Contractor shall ensure that all basic factual data is pseudonymised 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.

11.5 In the event that the Contractor does supply the Authority with Personal Data or Personal Data that has been pseudonymised or anonymised, the Contractor warrants to the Authority that:

11.5.1 Any Personal Data provided (whether by way of reporting progress or results or otherwise) is provided with the consent of the Data Subjects involved or on the basis of a specified legal justification; or

11.5.2 Any Personal Data that has been pseudonymised or anonymised before being provided has been pseudonymised or anonymised to the appropriate standard recommended by the Information Commissioner's Office from time to time;

And in each case, the Contractor further warrants that it may be used by the Authority without restriction.

11.6 The Contractor shall, at the request of the Authority, deposit both qualitative and quantitative Research Data in a relevant data archive subject to any reasonable delay necessary to enable the protection or exploitation of Foreground IP. The Contractor shall be under no obligation to deposit any Research Data to the extent it contains (a) Contractor's Background IP, Third Party IP or Foreground IP; or (b) Confidential Information of the Contractor or any third party.

11.7 In order to reflect the Authority's position on open access to research materials, where research materials recording the outcome of the Research or details of the progress of the Research are submitted for publication, the Contractor shall either:

11.7.1 subject to confidentiality requirements and to applicable data protection considerations, make all information and data (including but not limited to Research Data) on which the research materials are based available on an open access basis; or

11.7.2 include a statement with the research materials detailing how such information and data can be accessed.

the aforesaid open access requirements shall not apply to (a) the Contractor's Background IP, Excluded Property, Third Party IP or Foreground IP; or (b) Confidential Information of the Contractor or a third party.

12. RESEARCH PRACTICE AND ETHICS

12.1 Not used.

12.2 The Contractor shall (and shall procure that any Collaborator or Research Site shall) comply with all relevant legislation, if applicable to the Research 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

The Mental Capacity Act 2005.

12.3 The Contractor shall use (and shall 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 Insofar as it is relevant to the Research and 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 Insofar as it is applicable to the Research, the Contractor will provide the Authority's Representative with a copy of the Research Ethics Committee's favourable opinion and the HRA approval once they have been given

(whether unconditionally or subject to conditions) or inform the Authority's Representative if either is withheld.

12.6 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 the Deliverables and the Service Support) and SECTION 6. The Contractor acknowledges that the Authority may to suspend payments in accordance with Condition 3.6 in the event that (a) reasonable progress on the Research has not been maintained; or (b) any element of the Deliverables or the Service Support have not been provided as required; or reports have not been submitted as required under Condition 13; or (c) the Contractor has substantially failed to comply with the terms of this Contract (including where the Contractor has failed to procure that any of the Collaborators or Research Sites comply with certain obligations as required by this Contract).

13.2 The Contractor shall provide an interim written report on the progress of the Research according to the schedule set out in SECTION 6. The interim report shall be in a form and otherwise in compliance with the format set out by the Authority's Representative as amended from time to time and shall include an outline of the Research Data, methods, an outline of any Foreground IP, Arising Know How results, financial analysis relating to the outputs of the Research, Background IP and provisional conclusions together with management information, financial information relating to the costs and progress of the Research and any other relevant information relating to the Research up to the relevant date. Notwithstanding, Excluded Property is not required in interim reports (whether written or verbal) or in feedback under this Condition 13.

13.3 During the Research Period the Contractor shall provide verbal or written reports as reasonably required by the Authority or the Authority's Representative on any aspect of the Research.

13.4 During the Research Period, 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) and by offering such individuals other opportunities to provide feedback.

13.5 If the Contractor disputes the Authority's deduction of any sums under this Condition 13, the Contractor shall promptly notify the Authority in writing and the dispute shall be resolved in accordance with Condition 29.

14. FINAL REPORT

14.1 The Contractor shall provide a draft final report on the Research within FOURTEEN (14) CALENDAR DAYS of the Completion Date or date of termination howsoever terminated. The draft final report shall be in a form to be agreed with the Authority as amended from time to time or as otherwise required by the Authority's Representative and shall include an outline of the Research Data, methods, an outline of any Foreground IP, Arising Know How, results, Background IP and the final conclusions of the Research together with management information and any other information relating to the Research up to the Completion Date.

14.2 The Contractor shall also provide, in a form to be agreed with the Authority, a draft summary final report of the findings for the Research.

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

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

15. INTELLECTUAL PROPERTY RIGHTS

15.1 The Excluded Property is and shall remain the property of Contractor and/or the Contractor Affiliates. The Contractor acknowledges and agrees that the Collaborators and/or Research Sites shall be permitted to use the Zio Device, Zio Service and iRhythm Reports solely to provide medical treatment to patients and to generate Research Data pursuant to the terms of the relevant Collaborator Agreement. Save for the aforesaid, nothing in this Contract shall operate to:

15.1.1 transfer the ownership of the Excluded Property; or

15.1.2 grant any right of access or licence to the Authority or any third party (including any Collaborator or Research Site) to the Excluded Property; or

15.1.3 exclude or limit the Contractor's or the Contractor Affiliate's to develop any iRhythm Improvements or iRhythm Improved Products or any other Excluded Property;

15.1.4 exclude or limit the Contractor's or the Contractor Affiliates' right to use, exploit, or commercialise (including Commercial Use) the Excluded Property. The Contractor's or the Contractor Affiliates' ability to enter into commercial agreements for the supply of any iRhythm Products or iRhythm Improved Products with any Health Service Body or other healthcare organisation or healthcare professional shall not be limited by this Contract (save solely for the provision of Zio Devices or Zio Services pursuant to the terms and for the duration a Collaborator Agreement, which shall be in consideration for the payment of the Approved Cost); or

15.1.5 exclude or limit the Contractor's or the Contractor Affiliates' ability to prosecute, maintain, protect, enforce or defend their Intellectual Property subsisting in the Excluded Property.

15.2 Contractor Background IP is and shall remain the property of the Contractor (or, where applicable, the third party from whom its right to use the such Contractor Background IP is derived). The Contractor (or the relevant third party from whom its right to use is derived) shall be responsible for the prosecution, maintenance, protection, enforcement and defence of all Contractor Background IP.

15.3 Foreground IP, Arising Know How and Research Data that may arise from the Research shall vest in the Contractor unless the Contractor and the Collaborator (or Research Site as the case may be) have otherwise agreed in the relevant Contractor's Collaboration Agreement.

15.4 The Authority acknowledges and agrees that the Contractor may transfer (whether by licence or assignment) its rights in any Foreground IP, Arising Know How and/or Research Data to iRhythm Technologies, Inc. without the prior consent of the Authority.

15.5 The Contractor shall and shall ensure through each Collaborator Agreement that the Collaborator(s) and Research Sites shall keep detailed records including where relevant scientific notebooks of all of its activities and upon request shall make available copies to the Authority.

15.6 The Contractor shall make available the Contractor Background IP that is necessary or useful for undertaking the Research and the protection, dissemination or exploitation of the Foreground IP and Research Data. Where it is reasonable to do so and is an appropriate means of achieving Patient Benefit, the Contractor has responsibility for filing, prosecuting, maintaining, defending and enforcing protection for such Contractor Background IP, and shall retain this responsibility unless otherwise agreed in writing and in any event at no cost to the Authority. If the Contractor wishes to cease doing so in relation to any of such Contractor Background IP necessary for the dissemination, use or exploitation of the Foreground IP, it shall notify the Authority no less than two (2) months prior to discontinuing its maintenance, defence or enforcement of such Contractor Background IP. The Contractor shall licence or assign the Contractor Background IP to a nominee of the Authority's subject to such licence or assignment being made on fair and reasonable terms.

15.7 The Contractor shall use reasonable endeavours (subject to fair and reasonable licencing terms) to make available to the Collaborators and to the Authority the Third Party IP that is necessary or useful for undertaking the Research and the protection or exploitation of the Foreground IP, Arising Know How and Research Data.

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

15.8.1 use and publish (in accordance with Conditions 8 and 9):

(a) any information relating to the Research which is not Confidential Information of the Contractor;

(b) any Foreground IP;

(c) Research Data;

(d) Reports;

(e) Arising Know How; and,

(f) conclusions arising from the Research

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

15.8.2 use the Contractor's Background IP and Third Party IP but solely to the extent that it is necessary in order to exercise the licence granted in sub-Condition 15.8.1 above.

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

15.9 The Contractor shall ensure, and shall ensure that the Collaborator(s) shall 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.

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

16. EXPLOITATION OF INTELLECTUAL PROPERTY

16.1 The Contractor shall inform the Authority in a timely manner of any outcomes from the Research, including any Foreground IP, Arising Know How or Research Data, which are capable of exploitation either by direct adoption into the healthcare service or via commercialisation. Any information disclosed to the Authority (whether written or otherwise) under this Condition 16.1 shall be deemed to be the Contractor's Confidential Information and subject to Condition 9.

16.2 The Contractor shall develop, implement and maintain procedures for the management of Foreground IP, Arising Know How and Research Data and in particular, but without limitation, shall use all reasonable endeavours to ensure that:

16.2.1 the Foreground IP is identified and recorded;

16.2.2 it notifies the Authority within SIX (6) months of receipt of disclosure of potential patentable Foreground IP and in the event that the Contractor decides not to protect the invention by filing a patent application, the Contractor agrees to communicate this decision to the Authority and the Authority shall have the right but not the obligation to take assignment of the Intellectual Property associated with the disclosure free of charge and to manage the associated Intellectual Property, save that the Contractor may reasonably request an extension of up to one (1) year from the date of any such notification under this Condition 16.2 to enable further validation or development of the Foreground IP prior to protection;

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

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.

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;

16.2.6 all such patent applications are diligently prosecuted having regard to all relevant circumstances; and

in the event that the Contractor elects to abandon prosecution of a patent application protecting applications of the outcome of the Research (including the Foreground IP), the Contractor shall inform the Authority's Representative as soon as reasonably practical and in any event no less than two (2) months in advance of the patent application lapsing and the Authority shall have the right but not the obligation to take assignment of the Intellectual Property associated with the application free of charge and to manage its prosecution.

16.3 The Contractor shall permit the Authority to monitor the operation and effectiveness of the Contractor's procedures for the management of Intellectual Property in such ways as the Authority considers reasonably necessary to ensure that any Foreground IP generated is disseminated and/or exploited for the public benefit, subject to suitable confidentiality terms. This right shall include but not be limited to the right of the Authority (or its authorised representative) to inspect and audit the Contractor's records kept pursuant to Condition 16.4.3, subject to the Authority providing ten (10) Business Days' written notice to the Contractor and the Parties agreeing suitable confidentiality terms. This right of inspection and audit may be performed once in each twelve (12) month period following the Commencement Date. For the avoidance of doubt, the Authority's right to monitor, inspect and audit under this Condition 16.3 shall not extend to any Contractor Background IP, Third Party IP or Excluded Property.

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

16.4.1 where reasonable and practicable, promote the dissemination of the Foreground IP, Arising Know How and Research Data in order to achieve Patient Benefit;

16.4.2 where reasonable and practicable exploit such Foreground IP, Arising Know How and Research Data to generate either capital or revenue or both; and

16.4.3 keep proper records showing the description of the Contractor Background IP or Third Party Background IP used and Foreground IP generated.

16.5 The Contractor shall and shall procure that any Collaborator or Research Site shall notify the Authority if it or any Collaborator, as the case may be, makes any Commercial Use of, or permits any third party to make any Commercial use of the Foreground IP or Arising Know How or Research Data. The Contractor shall or shall procure that any Collaborator or Research Site shall provide all appropriate details of any proposed commercialisation arrangements, including but not limited to any deal sheet or commercial terms in circulation, which information the Authority shall keep confidential. The Authority shall within thirty (30) Business Days of such notice inform the Contractor and/or Collaborator if the Authority requires the Contractor and or Collaborator] to enter into a commercialisation agreement with the Authority.

16.6 Any such commercialisation agreement shall as a minimum:

16.6.1 address the distribution of revenue, equity or other benefits arising from the proposed commercialisation arrangements and rights to use the Foreground IP, Arising Know How or Research Data;

16.6.2 reflect the Authority's policy from time to time relating to the allocation and use of revenue, equity or other benefits arising from the proposed commercialisation arrangements and rights to use the Foreground IP, Arising Know How or Research Data;

16.6.3 take into consideration the relative contribution of the Authority, the Contractor, the Collaborator(s) and other third party funders or contributors to the Foreground IP, the Arising Know How or the Research Data.

16.7 Unless agreed otherwise in writing, the Contractor shall enter into good faith negotiations regarding any proceeds of commercialisation to be allocated to the Authority as a result of any Commercial Use of the Foreground IP, Arising Know How or Research Data and the terms of a revenue sharing agreement.

16.8 Conditions 16.6 and 16.7 shall not apply to any transfer of the Contractor's rights in the Foreground IP, Arising Know How or Research Data to iRhythm Technologies, Inc.

16.9 Nothing in this agreement shall entitle the Authority, Collaborator and/or Research Site to any revenue, payments, equity or other benefits from the exploitation or commercialisation (including Commercial Use) of the Contractor's Background IP, the Excluded Property, any Third Party IP (including any Intellectual Property of a Collaborator Affiliate).

16.10 In the event that the Contractor and/or a Collaborator commercialises Foreground IP, Arising Know How or Research Data then the Contractor and/or Collaborator must take due consideration of the Authority's attitude to access to essential health related technologies including medicines in the developing world.

16.11 If the Contractor does not reasonably protect, manage or exploit any Foreground IP arising out of the Research according to the terms of this Contract or if this Contract is terminated according to Condition 19.4, then the Authority shall have the right, acting reasonably and subject to the rights of third party licensees or Collaborators, but not the obligation, to take assignment of and protect, manage and exploit such Foreground IP. Such right shall be exercised no earlier than six (6) months after the Authority has given the Contractor notice in writing that it is failing to protect, manage and exploit such Foreground IP to the Authority's reasonable satisfaction. However, the Authority may exercise such right sooner where it reasonably considers that the opportunity to protect, manage or exploit such Foreground IP for the public benefit could be lost if more immediate action is not taken. The Contractor agrees to do, and will ensure that its employees, students and any third party acting on its behalf do, all acts required by the Authority to further such protection and exploitation including the delivery of all necessary written information including copies of any notebooks maintained throughout the Research.

16.12 If the Contractor wishes to use any third party (excluding its professional advisors) to carry out its obligations with respect to this Condition 16, which is different from that proposed in the Contractor IP Policy, then it must provide details of the proposed third party to the Authority and obtain the Authority's prior written approval to such third party carrying out exploitation activities with respect to the Foreground IP. The Authority may, by notice in writing, require the Intellectual Property to be promptly assigned to the Authority if the Contractor is subject to an Insolvency Event.

16.13 The Contractor shall do or procure to be done all such further acts and things and execute or procure the execution of all such other documents as the Authority may from time to time require for the purpose of giving the Authority the full benefit of the provisions of this Contract.

17. PUBLICATION

17.1 The Contractor shall (and shall procure that each member of staff engaged on the Research shall) use all reasonable endeavours to comply with the Authority's policy and guidance on the publication of research outputs which may be issued by the Authority from time to time (to the extent it is reasonable). This condition shall not apply where (a) the Contractor and/or Collaborator has a contractual, legal or similar obligation to publish specific details about the Contract or the Research or (b) the guidance requires the publication of Confidential Information. For the avoidance of doubt this obligation continues after the end of the Research Period.

17.2 In the event that the Contractor fails to comply with Condition 17.1 the Authority reserves the right to:

17.2.1 deem this to be a material breach and terminate this Contract in accordance with Condition 19.4; and/or

17.2.2 suspend or reduce its payment of amounts due under the payment schedule in SECTION 4 of the Contract; and/or

17.2.3 require repayment of all or part of the funding provided under this Contract.

17.3 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.

17.4 The Contractor shall comply, and shall ensure that the Collaborator(s) comply, with reasonable 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.

17.5 Subject to the provisions of Condition 9, 11, 13 and 14 and notwithstanding the provisions of Condition 15 and 16, the Authority's Representative may at any time publish the Reports for any non-commercial purpose and 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.

The Contractor shall assign to the Authority on behalf of the Crown all Intellectual Property rights 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 the copyright in the Report and does not extend to the Intellectual Property described therein.

17.6 The Contractor undertakes to obtain an assignment to the Authority of any Intellectual Property rights 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.

17.7 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 2020.

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".

17.8 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 AI in Health and Care Award, iRhythm Technologies, 1897. 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. Not used

19. TERMINATION UPON OCCURRENCE OF EVENTS

19.1 Without prejudice to any other provision of this Contract, this Contract may be terminated by either Party giving three (3) months' notice in writing to the other. Should the option to terminate be exercised by the Authority under this Condition 19.1, it shall indemnify the Contractor from and against all and any actual loss unavoidably incurred by reason or in consequence of the termination provided that the Contractor takes all immediate and reasonable steps to minimise the loss.

19.2 The Authority will not pay any sum under Condition 19.1 which, when taken together with any sums paid or due or becoming due to the Contractor under this Contract, will exceed such total sums as would have been payable under this Contract if the Contractor had fulfilled its obligations under this Contract.

19.3 The Authority may at any time by notice in writing terminate this Contract without liability for any damage, loss or expenses arising as a result of or in connection with such termination if there is a change of control (as defined by sections 450 and 451 of the Corporation Taxes Act 2010) in Contractor. The Authority shall be permitted to exercise its rights pursuant to this Condition 19.3 for only six (6) months after any such change of control and shall not be permitted to exercise such rights where the Authority has agreed in advance in writing to the particular change of control and such change of control takes place as proposed. The Contractor shall notify the Authority within two (2) weeks of any change of control taking place.

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

19.4.1 the Contractor is subject to an Insolvency Event; or

19.4.2 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

19.4.3 the Contractor fails to deliver the Service Support in accordance with SECTION 3 Part C and fails to remedy the failure within thirty (30) days of the service of a written notice by the Authority specifying the breach and requiring its remedy; or

19.4.4 an event of Force Majeure exists for more than six (6) months; or

19.4.5 in accordance with Condition 8.2 or 17.2 of this Contract; or

19.5 The Authority may terminate this Contract with immediate effect at any time:

19.5.1 if any member of the Contractor's Key Staff is not available to fulfil his part in the Research for any part of the Research Period, subject to prior discussion with the Contractor to first attempt to identify a mutually acceptable replacement;

19.5.2 if the Contractor is unable or unwilling for any reason to continue with the Research or if in the reasonable opinion of the Authority the Contractor is consistently failing to achieve an acceptable standard in relation to the Research in which case no financial compensation shall be payable to the Contractor.

20. CONSEQUENCES OF TERMINATION

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

20.1.1 release a Party from any duty or obligation of confidence under this Contract, in particular as imposed by Conditions 8 – 11 inclusive, which falls on it, or its sub-contractors, agents, employees or former employees, under this Contract or under the general law governing confidential information; or

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

21. EQUIPMENT

21.1 The Contractor shall take all practical steps to purchase all materials and equipment at a fair and reasonable price. The Authority may inspect the original quotations and invoices issued to the Contractor for equipment purchased in connection with the Research and recover any funds provided for the purchase if the Contractor does not provide this documentation on request.

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

22. FORCE MAJEURE

22.1 In the event that any Party is 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 insofar as it is performed by the Contractor and not a Collaborator or Research Site, it has, or has access to, sufficient resources to perform that aspect of 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 to the best of its knowledge and belief:

(a) except for the items listed in the declaration set out in SCHEDULE C, the Contractor has an unrestricted and free right to use and to make available the Contractor Background IP for the purposes of the Research;

(b) unless it is agreed in the relevant Collaborator Agreement that the Collaborator and/or Research Site to jointly own the Foreground IP with the Collaborator, it and/or a Collaborator the Contractor (or iRhythm Technologies, Inc.) will be the legal and beneficial owner(s) of all right, title and interest in and to the Foreground IP and where reasonable and practicable the Collaborator will own and manage such Foreground IP in accordance with, and subject to the terms of this Contract; and

(c) it has not granted any third party any right in respect of the Foreground IP (other than in accordance with the provisions of this Contract), and has not charged or encumbered and will not charge or encumber any of the same.

23.1.6 Insofar as the Research (including the Service Support) is carried out by the Contractor’s staff, it will be carried out by appropriately experienced, qualified and trained personnel with all due skill, care and diligence;

23.1.7 to the extent it is applicable, 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, Arising Know How or Research Data to the extent necessary to exercise any rights under, or to perform, this Contract;

23.1.8 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, Arising Know How, Contractor Background IP, and/or Third Party IP or any products derived from them, or their fitness for any purpose; or

23.2.2 with respect to any Excluded Products; or

23.2.3 that any material produced or supplied by any Party and any products, 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 23.7 the Contractor shall indemnify the Authority, its officers, servants and agents fully against any liability, loss, claim or proceedings whatsoever arising from an action brought by a third party against the Authority in respect of:

23.3.1 any damage to property, real or personal, including any infringement of third party Intellectual Property rights; and,

23.3.2 any injury to persons including injury resulting in death,

in both cases arising out of or in the course of, or in connection with the Contract and attributable to the Contractor. The aforesaid indemnity shall not apply to any liability, loss, claim or proceedings to the extent they are due to any act, omission or neglect of the Authority, or their officers, servants or agents.

23.4 Save as provided in Condition 23.8, the Contractor's total aggregate liability to the Authority in respect of all causes of action arising out of or in connection with this Contact (whether for breach of contract, strict liability, tort (including, without limitation, negligence), misrepresentation or otherwise) shall not exceed the amount paid in cleared funds by the Authority to the Contractor under this Contract (such amount shall not exceed four million eight hundred and thirty thousand pounds (£4,830,000) .

23.5 Notwithstanding any other provision of this Agreement, each Party shall use its reasonable endeavours to mitigate losses it may incur that are covered by indemnities provided by the other Party.

23.6 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 reasonably informed of the progress in respect of such claims, demands or action.

23.7 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.

23.8 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 and;

32.2.2 To the extent authorized by FOIA, 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 The Authority shall, after consulting with the Contractor, be responsible for determining in its absolute discretion, and notwithstanding any other provision in this Contract or any other agreement, whether the Commercially Sensitive Information and/or any other Information is exempt from disclosure in accordance with the provisions of the Code of Practice on Government Information, FOIA or the Environmental Information Regulations.

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 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, acting reasonably.

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

33.3.1 national security;

33.3.2 personal data;

33.3.3 information protected by intellectual property law;

33.3.4 third party or Collaborator confidential information;

33.3.5 IT security; or

33.3.6 prevention of Fraud.

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

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

34. UNLAWFUL DISCRIMINATION

34.1 The Contractor shall ensure that it complies with all current employment legislation and in particular, does not unlawfully discriminate within the meaning of the Equality Act 2010 or any other relevant legislation relating to discrimination in the employment of employees, for the avoidance of doubt this includes having due regard, where so required, for any additional equality duties imposed on public authorities (collectively, the "**Employment Legislation**").

34.2 The Contractor shall notify the Authority immediately of any investigation of or proceedings against the Contractor under the Employment Legislation 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

Each Party will, at the request of the of the other Party, do (or procure others to do) everything necessary to give the other Party 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.

38. ENTIRE AGREEMENT

This Contract expresses the entire agreement between the Parties. All prior negotiations, understandings, promises, assurances, warranties, representations and agreements, oral or written, are superseded and extinguished by this Agreement and both Parties hereby agree that in entering into this Contract they have not relied upon any previous understanding, statement, representation, assurance or warranty that is not set out in this Contract.

SCHEDULE A ASSIGNMENT

In consideration of the Authority's support for the Research detailed in the contract dated September 8, 2020 between the Contractor and the Secretary of State for Health and Social Care ("the Contract"), I/we iRhythm Technologies Limited hereby assign all Intellectual Property rights in the Reports which exist now or come into existence in the future and to which I am / we are legally entitled defined in the Contract to the Secretary of State for Health and Social Care on behalf of the Crown.

Signed by: [redacted]

Date: November 17, 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

iRhythm Technologies Limited ("the Contractor") dated September 8, 2020 ("the Contract")

Variation No: _____

Date: _____

1. In consideration for the sum of £1 (receipt of which the Authority acknowledges) and the mutual promises set out in this variation contract, the Authority and Contractor agree to amend the Contract 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 SCHEDULE OF ENCUMBERED OR RESTRICTED BACKGROUND IP

Description of Background IP	Owner of relevant Background IP	Nature of restriction	Risk to Research and outcomes
		None	

SCHEDULE D SCHEDULE OF ANTICIPATED FOREGROUND IP ARRANGEMENTS

For use only in those contracts where the Contractor will not be the sole owner of arising Foreground IP, and all/some Foreground IP will be held by a Collaborator(s).

This schedule should be used to set out at the Commencement Date all parties agreed intentions with regard to Foreground IP ownership and the resulting management and licensing mechanism to be put in place.

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. The Authority may:

a. withhold payments and/or reclaim any part of the payments paid to the Contractor to the extent necessary to ensure that any assistance given under this Contract taken together with any other assistance which, in the Authority's opinion, has been or is likely to be received towards the Research, is within the State Aid limits laid down by State Aid Legislation; and

b. vary, withhold or recover from the Contractor any part of the payment under this Contract with interest at the rate set by the European Commission, calculated from the date the relevant monies were made available to the Contractor, if required to do so under State Aid Legislation and/or any decision of the European Commission, provided that the Authority may not recover any part of the payment already recovered.

4. If any payment made under this Contract is considered to be unlawful state aid by any of the European Commission, the European Court of Justice or any national court and an order for its repayment is made, the Contractor will repay the relevant payment within fifteen (15) days of demand together with any such interest as may be applicable.

SECTION 3 RESEARCH

Part A: Research and Collaborators

i. Zio Service and Zio Reports

Zio Service

The subject of the Research is the Zio ECG monitoring service ("**Zio Service**"), which is a cardiac monitoring system used to detect all types of cardiac arrhythmias. The Zio Service is proprietary to iRhythm Technologies, Inc., an affiliate of the Contractor.

The Zio Service comprises three components:

- Zio biosensor: a single lead ambulatory electrocardiogram
- ZEUS: a proprietary, regulated, AI-enabled software platform, using deep neural network, that stores, analyses and curates the ECG data to generate a report, combined with online and mobile portal capabilities to support clinical workflows
- Zio technical report: a clinically actionable summary of the recorded ECG data.

The Zio Service is intended to replace or enhance the current assessment pathway for cardiac arrhythmia detection in people with palpitations, fainting (syncope) and suspected cardiac arrhythmia, such as AF. The Zio biosensor is placed on the person's chest and records continuous beat-to-beat ECG for up to 14 days. The device is designed to facilitate patient compliance and thereby improve data collection.

Without external leads or wires, noise artefacts are reduced in the data and the wearer may go about normal daily activities, including light exercise or showering, without required monitor maintenance. Each Zio biosensor is intended for single-patient use. After the monitoring period, the wearer removes the biosensor and sends it to the company by freepost. The ECG recordings are analysed using the clinically-validated, AI-based algorithm within ZEUS.

All AI algorithm results are reviewed for accuracy by iRhythm's highly trained cardiac physiologists using proprietary analysis software. After completing curation, the company physiologists produce a technical report (see Zio Reports below). If an urgent arrhythmia is detected, iRhythm Cardiac Technicians place an immediate call to alert the clinician (MDN – MD notification). The biosensor contains no patient identifiers and data cannot be accessed if the biosensor were to be physically intercepted

The evidence for the Zio Service is currently being evaluated by NICE under its new Digital Technologies Programme. The resulting guidance is due to be published in December 2020.

Zio Reports

The Zio Service may only be accessed by licensed medical practitioners who are authorised by the Collaborator or Research Site to prescribe the Zio Service to patients. These authorised medical practitioners will be able to receive a technical report containing information regarding arrhythmia episodes, wear and analysis time and other patient-captured events captured from the Zio Device ("**Zio Report**"), which is sent via an online secure portal to the prescribing clinician for final diagnosis.

A report setting out aggregated data and statistics from the relevant Collaborator or Research Site's use of the Zio Device during a four-month period will be provided to the relevant Collaborator or Research Site ("**Zio Service Report**").

ii. Collaborators

The list of Collaborators is set out below. Whether a Collaborator participates in the Research will depend on each Collaborator's (and each Research Site's) readiness and ability to participate (including the impact on local arrangements due to COVID-19).

The timing of each Collaborator's participation in the programme may vary, depending on the level of readiness of each site. As of the Commencement Date, it is expected that 'Phase I' Research Sites will be ready to commence participation in the programme by January 2021.

Collaborators are currently identified as:

1. Liverpool Heart and Chest NHS Trust
2. South Tyneside and Sunderland NHS Foundation Trust
3. Northamptonshire CCG
4. Staffordshire STP
5. Gloucestershire Hospitals NHS Foundation Trust
6. Cheshire and Merseyside Stroke Network (involving specific trusts within this network, depending on readiness)
7. North Bristol NHS Trust
8. Hillingdon Hospital Foundation Trust
9. King's College Hospital NHS Foundation Trust
10. Barts Health NHS Trust
11. Southampton NHS Trust
12. Guy's and Thomas' NHS Foundation Trust
13. St George's Hospital NHS Foundation Trust
14. Addenbrookes' Hospital NHS Trust
15. Royal Brompton NHS Trust

iii. Research Framework:

The Research to be conducted under this Contract is described below.

a. AI Award

The Contractor has been awarded an AI Award by NHS England and NHSx. Pursuant to the delivery of the Award, the Contractor and Evaluators appointed by NHS England shall work with the Contractor: (i) to define a precise scope of evaluation metrics by no later than the end of the first quarter of 2021; and, (ii) determine participating sites which will be evaluated fully.

Such evaluation metrics are not part of any Deliverables or key outcome measures that are required to be reported to the Authority under Condition 13.1 and do not form part of the monitoring process relating to the conduct of the Research.

b. Purpose of the Research

The purpose of the Research is to obtain, through the clinical and operational evaluation of the ZIO Service within routine NHS pathways, new evidence on the ZIO Service from the Key Outcome Measures and Deliverables defined in this Research Contract. This new evidence will build on the current evidence-base of diagnostic testing currently available to [UK healthcare organisations and commissioning groups] to help them make decisions around the large-scale commissioning or deployment of the ZIO Service within the NHS. Specifically, the new evidence obtained under this Research will be used to (a) address gaps in efficacy or accuracy; and (b) and to assess the clinical and economic impact of the ZIO Service.

iv. Key outcome measures to be considered for the evaluation

- Diagnostic Yield
    - Arrhythmia (including atrial fibrillation) detection rate (% patients with arrhythmia)
    - Arrhythmia 'rule out' rate (% patients with no symptoms and no arrhythmia)
- Time to first symptomatic arrhythmia
- Time from referral to test result
- Number of repeat tests required
- Stroke/TIA patients: Post-index event (Stroke) - Time to ambulatory ECG monitoring
- Number of outpatient appointments and visits required for testing
- Patient satisfaction
- Customer/User satisfaction
- Patient Compliance (wear time/analysable time)
- Number of in-clinic outpatient follow up appointments
- Number of Virtual outpatient follow up appointments
- Number of amend requests (excluding demographic)
- Number of fast track Medical Director Notifications (MDNs)

Part B: Deliverables and Key Milestones

i. Deliverables:

The Deliverables will be in the form of a quarterly report provided by iRhythm to the AI Awards team. The report will contain:

- The total number of Zio Service patient cycles of care* that took place during that quarter; and
- Breakdown of number of cycles of care* by the Research Site and/or Collaborator.

*Each cycle of care is described as:

ii. The Zio biosensor is fitted to the patient (either by the health care professional or by the patient or carer if fitted at home)

iii. The Zio biosensor is worn by the patient for up to 14 days and then removed and posted (in pre-paid box) to iRhythm.
iv. ECG data collected on the biosensor is analysed by proprietary, cloud-based artificial intelligence algorithm and reviewed by iRhythm Cardiac Technicians
v. The Zio Report is uploaded to a secure website (within 4 business days of biosensor receipt) where the prescribing clinical can review it and provide the final diagnostic interpretation.

ii. Key milestones:

The timelines below are indicative and not binding on the Contractor. The Contractor shall agree the scope of the milestones and the timetable with the Evaluator and notify the Authority in accordance with Condition 6.

Milestone	**Due date**
Financial forecast	Oct 16 2020
Evaluation framework agreed	Oct 16 2020
Local site agreements in place	
- Phase I sites	Q1 2021
- Phase II sites	Q2/Q3 2021
- Phase III sites	Q4 2021
Metrics agreed	
• Deployment metrics (process measures and timings) based on patient cycles of care	Oct 2020
• Impact metrics (outcome measures and timings) based on ZSR and other metrics agreed	Dec 2020
Quarterly reporting (deliverables)	Quarterly
Project plan and milestone review and update – sign-off	April 2021

Part C: Service Support and Continuity

The Research is anticipated to run for 36 months beginning on Commencement Date and concluding on the Completion Date.

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.[1]

Project Quarter	Date	Amount (£)
Q1	31-Oct-20	[redacted]
Q2	31-Jan-21	[redacted]
Q3	30-Apr-21	[redacted]
Q4	31-Jul-21	[redacted]
Q5	31-Oct-21	[redacted]
Q6	31-Jan-22	[redacted]
Q7	30-Apr-22	[redacted]
Q8	31-Jul-22	[redacted]
Q9	31-Oct-22	[redacted]
Q10	31-Jan-23	[redacted]
Q11	30-Apr-23	[redacted]
Q12	31-Jul-23	[redacted]
	TOTAL	**£4,830,000**

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.

[1] The Contractor will earn 75% of the imputed cost of a cycle of care (i.e., 75% of £302.00) on the delivery of Zio Devices to the Contractor's UK warehouse. The Contractor will earn the remaining 25% of the imputed cost of a completed cycle of care upon delivery of the quarterly reporting as detailed in Section 3. The Authority acknowledges and agrees that the Zio Service is the provision of a service and that the Contractor shall have earned and be entitled to be paid (and the Authority shall be liable to pay the Contractor) for the costs for each cycle of care relating to each Zio Device supplied pursuant to this Contract (or any Contractor's Collaboration Agreement).

SECTION 5 KEY STAFF

(a) The Contractor's representative name and address

[redacted] – iRhythm Technologies, Ltd., Seal House, 56 London Rd, Bagshot GU19 5HL

(b) The Authority's Representative for contract management purposes

[redacted] - NHSX

(c) The Authority's Representative for project management purposes

[redacted] NHS England and NHS Improvement

SECTION 6 REPORTING SCHEDULE AND FORM OF REPORTS

Part A – Reporting Schedule

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

1. Quarterly report
2. Formal quarterly review meetings
3. Monthly high level update reports
4. Final Report

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

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

Report	Due date
Monthly reports	At the end of every month during the term of this Contract until the Final Report. The Contractor is not obliged to provide a monthly report if a quarterly report or Final Report is due in the same month.
First quarterly report	Within 3 months of the date of first site enrolment
Subsequent quarterly reports	Every [3] months after the first quarterly report
Final Report	As described in Condition 14.1

Part B – Form of Reports

A report from the Contractor, providing the feedback outlined in Part A.