

DATED 19 October 2020

(1) DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY

(2) ROYAL FREE LONDON NHS FOUNDATION TRUST

PROJECT SERVICES AGREEMENT

THIS AGREEMENT dated 19 October 2020 is between:-

- (1) **DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY** of 1 Victoria Street, London SW1H 0ET (the "**Authority**"); and
- (2) **ROYAL FREE LONDON NHS FOUNDATION TRUST** of Pond Street, London NW3 2QG ("**Royal Free**"),

each a "**Party**" and together the "**Parties**".

WHEREAS:-

- A. The Authority, by means of the 'Vaccines Taskforce', is involved in finding a solution to the SARS CoV-2 pandemic (the "**Pandemic**"), and is supporting and investing in vaccine programmes, as well as in building lasting health and economic benefits for the United Kingdom. The Authority sees the support of, investment in, and access to, human challenge studies as being an essential means by which these objectives may be met.
- B. Royal Free is a pioneering healthcare organisation, playing a leading role in the care of patients. Royal Free is also actively involved in the efforts to understand and find a solution to the Pandemic.
- C. The Parties wish to use their collective expertise to collaborate on a project which aims to conduct GMP manufacture of SARS-CoV-2 virus generated from isolates, and design and carry out a study to characterise such virus in a human characterisation study (which will be conducted in accordance with GCP) to enable the development of a human challenge model specific to SARS CoV-2 (the "**Project**")
- D. This Agreement governs the services to be provided by Royal Free in respect of the Project. The Parties will execute a separate Project Collaboration Agreement with other Project Partners to agree the governance framework and other rights and obligations that will govern the operational and other aspects of the Parties' collaboration in relation to the Project.

IT IS AGREED as follows:-

1. DEFINITIONS

1.1 As used herein, the following terms shall be defined as follows:

"Applicable Laws"	means all applicable laws, statutes, and regulations and all judgments or orders of any applicable court or competent authority or tribunal;
"Bribery Laws"	means the Bribery Act 2010 and associated guidance published by the Secretary of State for Justice under the Bribery Act 2010 and all other applicable United Kingdom laws, legislation, statutory instruments and regulations in relation to bribery or corruption and any similar or equivalent laws in any other relevant jurisdiction;
"Business Continuity Plan"	means the business continuity and disaster recovery plan for the Services (and the people and facilities used to provide them) to minimise the effect of any unplanned interruption or event that would significantly impact on the ability of Royal Free to perform the Services, in whole or in part, in accordance with the terms of this Agreement;
"Business Day"	means a day other than a Saturday, Sunday or bank or public holiday in England;

"Capital Investment"	has the meaning given to it in Schedule 7;
"Cardiology Services"	means the cardiology services to be provided by Royal Free to the Recipient as more particularly described in Schedule 8;
"Catering Services"	means the catering services to be provided by Royal Free to the Recipient as more particularly described in Schedule 1;
"Characterisation Study" or "Study"	means the first-in-human study for the characterisation of SARS-CoV-2;
"Commencement Date"	19 October 2020 +
"Confidential Information"	any background Know-how, any of the Results and/or any other information disclosed by a Party to the other Party for use in the Project or under this Agreement which, by its nature or from the circumstances of its disclosure, should reasonably be presumed to be confidential;
"Data Loss Event"	any event that results, or may result, in unauthorised access to Personal Data (as defined in Schedule 6) held by Imperial under this Agreement, and/or actual or potential loss and/or destruction of Personal Data in breach of this Agreement, including any Personal Data Breach (as defined in the Data Protection Act 2018);
"DPA 2018"	means the Data Protection Act 2018;
"Data Protection Impact Assessment"	an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data;
"Data Protection Legislation"	<p>(a) the GDPR and any applicable national implementing laws as amended from time to time;</p> <p>(b) the DPA 2018 to the extent that it relates to processing of personal data and privacy; and</p> <p>(c) all applicable law about the processing of personal data and privacy;</p>
"EIRs"	the Environmental Information Regulations 2004 (SI 2004/3391) together with any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such regulations;
"FOIA"	the Freedom of Information Act 2000 together with any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such legislation;
"GCP"	means ICH Good Clinical Practice in accordance with the set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects as set forth in the International Conference on Harmonisation (ICH) guidelines 'Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance' and implemented by Directive 2001/20/EC, as amended, the Clinical Trials Directive, and Directive 2005/28/EC, the GCP Directive and other equivalent foreign regulations or standards, as applicable, as such standards, practices, procedures, requirements and regulations may be amended and implemented in the United Kingdom from time to time;

"GDPR"	means the General Data Protection Regulation (EU Regulation 2016/679);
"GLP"	means Good Laboratory Practice, the current good laboratory practices within the meaning of Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version) and Directive 2004/9/EC on the inspection and verification of good laboratory practice (GLP) (codified version) (together the GLP Directives) and other equivalent regulations or standards, as applicable, as such current good laboratory practices, regulations and equivalent foreign regulations or standards may be amended and implemented in the United Kingdom from time to time;
"Hard and Soft FM Services"	means the hard and soft facilities management services to be provided by Royal Free to the Recipient as more particularly described in Schedule 2;
"Human Challenge Steering Committee"	means the Project's operational governing and advisory committee (including in relation to the scope, budget and timelines of the Project), established by the Authority in accordance with clause 4 of the Project Collaboration Agreement;
"HVIVO"	means HVIVO Services Limited of Queen Mary Bioenterprises Innovation Centre, 42 New Road, London, E1 2AX;
"Imperial"	means Imperial College of Science Technology And Medicine of Exhibition Road, South Kensington, London SW7 2AZ
"Information"	has the meaning given under section 84 of FOIA;
"Intellectual Property Rights"	means copyright, patents, rights in inventions, rights in Confidential Information, Know-how, trade secrets, trade marks, service marks, trade names, design rights, rights in get-up, database rights, rights in data, semi-conductor chip topography rights, mask works, utility models, domain names, rights in computer software and all similar rights of whatever nature and, in each case: (i) whether registered or not, (ii) including any applications to protect or register such rights, (iii) including all renewals and extensions of such rights or applications, (iv) whether vested, contingent or future and (v) wherever existing;
"Know-how"	means inventions, discoveries, improvements, processes, formulae, techniques, specifications, technical information, methods, tests, reports, component lists, manuals, instructions, drawings and information relating to customers and suppliers (whether written or in any other form and whether confidential or not);
"Lease"	means the lease between (1) Royal Free London NHS Foundation Trust and (2) Secretary of State for Housing, Communities and Local Government , dated on or around the same date as the Project Collaboration Agreement;
"Pathology Services"	means the pathology services to be provided by Royal Free to the Recipient as more particularly described in Schedule 3;
"Performance Standard"	means the performance standards set out for each Service in the applicable Service Schedule, if any;
"Pharmacy"	means the pharmacy services to be provided by Royal Free to the Recipient as

"Services"	more particularly described in Schedule 4;
"Premises"	means [REDACTED] (903.74 Sqm) and Logistics space (88.49 Sqm) Royal Free Hospital, Pond Street, Hampstead NW3 2QG as demised under the Lease Agreement;
"Project"	has the meaning given to it in the Recitals to this Agreement;
"Project Collaboration Agreement"	means the Project collaboration agreement to be entered into by the Project Partners;
"Project Manager"	means the individual appointed by each Party from time to time to manage the Services as a whole;
"Project Partners"	means Royal Free, HVIVO and Imperial engaged by the Authority to provide expertise, services and other inputs for the Project;
"Project Plan"	means the plan set out in Schedule 2 of the Project Collaboration Agreement and as updated by the Parties in accordance with the Project Collaboration Agreement;
"Protective Measures"	appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the such measures adopted by it;
"Protocol"	means the protocol for the Characterisation Study;
"Radiology Services"	means the radiology services to be provided by Royal Free to the Recipient as more particularly described in Schedule 5;
"Recipient"	means for each Service, BEIS and/or HVIVO, as applicable;
"Rectification Period"	means the defined period in which response or rectification is required in respect of a Service as set out in a Remediation Notice;
"Remediation Notice"	means a notice issued by the Recipient pursuant to clause 7.7;
"Remediation Plan"	means a plan agreed pursuant to clause 7.8;
"Representative"	means the representative appointed by Royal Free for the Services;
"Results"	means all results, data, deliverables information and outcomes arising from the Projects, including the Study;
"Request for Information"	a request for information or an apparent request under the Code of Practice on Access to Government Information, FOIA or the EIRs;
"Royal Free Personnel"	means all employees, staff, other workers, agents and consultants of Royal Free and of any sub-contractors who are engaged in the provision of the Services from time to time;
"Service"	means an agreement entered into by or on behalf of the Authority and an individual Project Partner in relation to any services provided by such Project

"Agreement"	Partner in respect of the Project aspect of the Project and "Service Agreements" shall be construed accordingly;
"Service Charges"	the charges to be paid for the Services as set out in the applicable Services Schedule;
"Service Failure"	means a failure by Royal Free to meet the relevant Performance Standard in respect of any Service which is not rectified within the relevant Rectification Period;
"Service Manager"	means, in relation to each Service, the service manager appointed as such by each Party and notified to the other in accordance with Clause 7.1;
"Service Schedule"	means each schedule attached to this Agreement providing further details of the Services;
"Services"	means the Cardiology Services, the Catering Services, the Hard and Soft FM Services, the Pharmacy Services, the Pathology Services and the Radiology Services (and a reference to "Service" means anyone of the Services); and
"Study Delivery Team"	means the team responsible for the Project's operational management, as established by the Authority in accordance with clause 3 of the Project Collaboration Agreement.

2. TERM

- 2.1 The Parties agree to work collaboratively and in good faith to achieve the aims of the Project efficiently, in a timely fashion, and with due regard to the overriding purpose of finding a solution to the Pandemic.
- 2.2 This Agreement shall commence on the Commencement Date and shall continue, subject to earlier termination in accordance with its terms, until 31 August 2021 ("**Initial Term**") and will continue thereafter until terminated by either Party giving not less than 3 months' written notice of termination to the other, such termination to take effect no earlier than expiry of the Initial Term or at any time thereafter. For the avoidance of doubt, the earliest date at which such notice may be issued by either Party is 31 May 2021.

3. THE SERVICES

- 3.1 In its capacity as a partner to the Project and in consultation with the Authority and other Project Partners, Royal Free will provide the Services to the Recipient at the Premises in accordance with the terms of this Agreement.
- 3.2 In providing the Services, Royal Free shall at all times:
- 3.2.1 deliver the Services to the Recipient as set out in the applicable Service Schedule and shall meet or exceed the Performance Standards;
 - 3.2.2 provide the Services with reasonable skill and care;
 - 3.2.3 provide the Services in accordance with all Applicable Laws;
 - 3.2.4 obtain, maintain and comply with all consents;
 - 3.2.5 allocate sufficient resources to provide the Services in accordance with the terms of this Agreement;

- 3.2.6 comply with standard NHS policies and procedures; and
 - 3.2.7 deliver the Services in accordance with Royal Free standard operating procedures unless otherwise detailed otherwise in this Agreement.
- 3.3 Royal Free shall be responsible for and bear all costs incurred in putting in place any contracts required by Royal Free to enable it to provide the Services.
- 3.4 Royal Free shall have and maintain throughout the term of this Agreement a Business Continuity Plan. Royal Free shall ensure that it is able to implement the provisions of the Business Continuity Plan at any time in accordance with its terms.
- 4. **ROYAL FREE PERSONNEL**
- 4.1 At all times, Royal Free shall ensure that:
 - 4.1.1 each of the Royal Free Personnel is suitably qualified, adequately trained and capable of providing the applicable Services in respect of which they are engaged; and
 - 4.1.2 there is the required number of Royal Free Personnel to provide the Services properly;
 - 4.1.3 only those people who are authorised by Royal Free are involved in providing the Services.
- 5. **RECIPIENT OBLIGATIONS**
- 5.1 The Recipient shall:
 - 5.1.1 co-operate with Royal Free in all matters relating to the Services; and
 - 5.1.2 provide, in a timely manner, such information as Royal Free may reasonably request and the Recipient considers reasonably necessary in order to carry out the Services, and ensure that it is accurate in all material respects.
- 5.2 If Royal Free's performance of its obligations under this Agreement is prevented or delayed by any breach of the terms of this Agreement by the Recipient, its agents, subcontractors, consultants or employees:
 - 5.2.1 Royal Free shall be relieved from any relevant Performance Standards to the extent that it is unable to adhere to such Performance Standards as a result of the relevant breach; and
 - 5.2.2 Royal Free shall not be liable for any costs, charges or losses sustained or incurred by the Recipient that arise directly or indirectly from such prevention or delay.
- 5.3 The Recipient shall licence back to Royal Free the use of three bedrooms including three beds (as outlined in red on the plan attached as Appendix 4 to Schedule 2) until and including 28 February 2021 with the option for Royal Free to end this licence earlier on 31 January 2021 if conditions allow, subject to and at all times Royal Free observing the terms of the Lease in respect of its use of three bedrooms.
- 6. **CHANGES TO THE SERVICES**
- 6.1 If either Party wishes to change the scope or execution of the Services, it shall submit details of the requested change to the other in writing.

- 6.2 If the Recipient requests a change to the scope or execution of the Services, Royal Free shall, within a reasonable time (and in any event not more than ten (10) Business Days after receipt of the Recipient's request), provide a written estimate to the Recipient of:
- 6.2.1 the likely time required to implement the change;
 - 6.2.2 the likely effect of the change on the other Services (if any); and
 - 6.2.3 any other impact of the change on this Agreement.
- 6.3 Notwithstanding clause 6.2, Royal Free may, from time to time with prior written notice, change the Services in order to comply with any applicable safety or statutory requirements, provided that such changes do not materially affect the nature, scope of the Services.
7. **SERVICE MANAGEMENT**
- 7.1 Each Party shall appoint a Project Manager and Service Managers for the purposes of this Agreement through whom the Services shall be managed day-to-day and shall notify the other Party in writing of the identities of such Project Manager and Service Managers within 30 days' of the Commencement Date.
- 7.2 Royal Free shall nominate two (2) Royal Free representatives to each of:
- 7.2.1 the Study Delivery Team, in accordance with the process set out in Clause 3 of the Project Collaboration Agreement; and
 - 7.2.2 the Human Challenge Steering Committee, in accordance with the process set out in Clause 4 the Project Collaboration Agreement,
- in each case including Royal Free's Project Manager and the deputies to Royal Free's Project Manager.
- 7.3 Both Parties shall ensure that appropriate resource is made available on a regular basis such that the aims, objectives and specific provisions of this Agreement can be fully realised.
- 7.4 The Project Managers shall have regular weekly meetings (each a "**Review Meeting**") to monitor and review the performance of this Agreement, the achievement of the Performance Standards and the provision of the Services. Such Review Meetings may be attended by Service Managers, as appropriate. Review Meetings shall be minuted by Royal Free's Project Manager and copies of those minutes shall be circulated to both parties within ten (10) Business Days of each Review Meeting.
- 7.5 Prior to each Review Meeting, the Recipient's Project Manager shall notify Royal Free's Project Manager, and vice versa, of:
- 7.5.1 any problems relating to the provision of the Services as notified to them by any Service Managers;
 - 7.5.2 any changes in respect of the Services that are proposed or have been implemented since the last Review Meeting; and
 - 7.5.3 any other matters, for discussion at the next Review Meeting.
- 7.6 At each Review Meeting, the Parties shall agree a plan to address such problems and matters as have been identified pursuant to clause 7.5. In the event of a failure to agree on such plan, clause 7.7 shall apply.

7.7 In the event of either:

7.7.1 a Service Failure; or

7.7.2 a failure to agree an appropriate course of action to deal with any issue that is raised in a Review Meeting in relation to the Services (pursuant to clause 7.6),

the Recipient may give a written notice (a "**Remediation Notice**") to Royal Free which shall specify the Service Failure or issue in outline and the actions it reasonably considers Royal Free needs to take with respect to remedying the Service Failure or other issue.

7.8 Within ten (10) Business Days of receipt of a Remediation Notice, Royal Free shall submit a draft plan (a "**Remediation Plan**") in respect of the issues set out in the Remediation Notice. The Recipient shall either approve the draft Remediation Plan within five (5) Business Days of its receipt, or it shall inform Royal Free why it cannot accept the draft Remediation Plan. In such circumstances, Royal Free shall address all such concerns in a revised Remediation Plan, which it shall submit to the Recipient within five (5) Business Days of its receipt of the Recipient's comments. If no such notice is given, Royal Free's draft Remediation Plan shall be deemed to be agreed.

7.9 Once a Remediation Plan is agreed by the Parties, Royal Free shall immediately start work on the actions set out in the Remediation Plan.

7.10 Any failure to agree a Remediation Plan in accordance with clause 7.8 shall be dealt with in accordance with clause 22.

8. **SERVICE CHARGES**

8.1 In consideration of the provision of the Services, the Authority shall pay the Service Charges to Royal Free in accordance with the terms of this clause 8.

8.2 Royal Free shall issue its invoice in relation to the Services as follows:

8.2.1 in respect of the Hard and Soft FM Services (and rental costs for the Premises), [REDACTED]; and

8.2.2 for all other Services, [REDACTED].

8.3 The Authority shall pay all undisputed invoices in full in cleared funds within thirty (30) days of receipt of each properly submitted invoice in pounds Sterling to the bank account nominated by Royal Free:

[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]

VAT Number GB654946987

All remittance advice should be emailed to: [REDACTED]

- 8.4 The Authority shall pay any applicable UK Value Added Tax ("VAT") to Royal Free on receipt of a valid VAT invoice.
- 8.5 Where undisputed sums due hereunder are not paid in full by the due date Royal Free may, without limiting its other rights, charge interest at the applicable rate under the Late Payment of Commercial Debts (Interest) Act 1998, provided that Royal Free shall first give the Authority not less than 40 days' written notice of its intention to charge interest, such notice being served no earlier than the due date for payment of the relevant overdue sum. Interest shall accrue on a daily basis, and apply from the due date for payment until actual payment in full, whether before or after judgment. The Parties agree that this clause 8.5 is a substantial remedy for late payment of any sum payable under this Agreement in accordance with section 8(2) of the Late Payment of Commercial Debts (Interest) Act 1998.
- 8.6 If the Authority disputes any portion of an invoice, the Authority shall pay the undisputed portion of the invoice in full in accordance with clause 8.3. Within ten (10) Business Days of the Authority becoming aware of the reasons for any such dispute, the Authority shall notify Royal Free in writing, specifying the reasons for disputing the invoice. Royal Free shall provide all evidence as may be reasonably necessary to verify the disputed invoice. If the Authority determines that any sums are due to Royal Free, then Royal Free shall be entitled to issue an invoice in respect of such sums and the Authority shall pay such sums within thirty (30) days of receipt of the relevant invoice.
- 8.7 Unless otherwise expressly set out in this Agreement, the obligation to pay the Service Charges shall constitute the Authority's entire payment liability to Royal Free in respect of amounts payable for the delivery of Services under this Agreement.
- 8.8 The expected payment timetable and invoice amounts in respect of Hard and Soft FM Services and Capital Investment is attached at Appendix 1 to Schedule 7.
9. **CAPITAL INVESTMENT**
- 9.1 The Parties agree that the provisions of Schedule 7 shall apply.
10. **WARRANTIES**
- 10.1 Each Party represents and warrants that it has the right, power and authority to enter into this Agreement and grant to the other Party the rights (if any) contemplated in this Agreement.
- 10.2 Royal Free represents and warrants to the Authority that:
- 10.2.1 it is not party to any agreement which would prevent it from fulfilling its obligations under this Agreement;
 - 10.2.2 it has all governmental, regulatory, and other approvals and licences necessary for it to perform the Services; and
 - 10.2.3 it has the necessary skill, experience and resources to carry out the Services in a timely manner.

11. **CONFIDENTIALITY AND PUBLICATION**

- 11.1 The Parties recognise that the conduct of the Project and fulfilment of this Agreement may require the transfer of Confidential Information between the representatives. It is therefore agreed that each Party shall, and shall procure that its representatives shall, retain in confidence the Confidential Information received from other representatives during the term of this Agreement and for a period of 5 years from its termination or expiry. Each Party shall, and shall procure that its representatives shall use such Confidential Information only for the Project and for no other purpose.
- 11.2 The obligations of confidentiality set forth herein shall not apply to any information or materials to the extent that such information or materials:
- 11.2.1 are required to be disclosed by order of a court of law or appropriate government agency provided that the recipient inform the disclosing Party as soon as possible and the disclosing Party be given the opportunity, if time permits, to make appropriate representations to such court, authority or stock exchange or take such action as it feels necessary, at its cost, to attempt to secure the information is kept confidential;
 - 11.2.2 are submitted to governmental agencies to facilitate the issuance of marketing approvals or other regulatory approvals for products which emerge from the Project;
 - 11.2.3 are reasonably required to be disclosed to professional advisers (such as patent agents in the filing, prosecution and issuance of patents as permitted under the terms of this Agreement);
 - 11.2.4 have been approved for publication by the Parties; or
 - 11.2.5 are product-related information which is reasonably required to be disclosed in connection with marketing or sub-licensing activities with respect to products.
- 11.3 The Parties agree that all proposed publications that discuss or disclose any part of the Results will be submitted to the Human Challenge Steering Committee and governed by the publication terms in the Project Collaboration Agreement.
- 11.4 Subject to clause 11.3, the Parties agree that they will not make any public announcements, press releases or otherwise publicise any matters discussed by the Human Challenge Steering Committee or relating to the Project without the prior approval of the Human Challenge Steering Committee.
- 11.5 No Party shall use the name of any other Party in any form of publicity, advertising or promotion without the written permission of that Party. Such approval shall not be unreasonably withheld and if given shall be given promptly. Nothing in this clause shall prevent a Party from using another Party's name when properly referencing use of publications or parts thereof.

12. **INTELLECTUAL PROPERTY RIGHTS**

- 12.1 Except as expressly set out in this Agreement:
- 12.1.1 the Authority shall not acquire any right, title or interest in or to the Intellectual Property Rights of Royal Free which existed before this Agreement or was developed independently of the Project (being "**Royal Free Background IPR**") or its licensors (being "**Third Party IPR**");
 - 12.1.2 Royal Free shall not acquire any right, title or interest in or to the Intellectual Property Rights of the Authority which existed before this Agreement or was

developed independently of the Project (being "**Authority Background IPR**") or its licensors;

- 12.1.3 all Results and all Intellectual Property Rights in and to the Results (being "**Project Specific IPR**") shall be the property of the Authority; and
- 12.1.4 all Protocols and all Intellectual Property Rights therein shall remain the property of the Authority and Royal Free shall not acquire any right, title or interest or Intellectual Property Rights of whatever nature in the same or in any copies.
- 12.2 Where either Party acquires, by operation of law, title to Intellectual Property Rights that is inconsistent with the allocation of title set out in clause 12.1, it hereby does assign and where such Intellectual Property Rights cannot be prospectively assigned, shall assign in writing such Intellectual Property Rights as it has acquired to the other Party on the request of the other Party (whenever made).
- 12.3 Royal Free hereby transfers to the Authority, or shall procure the transfer to the Authority of, all rights (subject to clause 12.1.1) in the Project Specific IPR.
- 12.4 Royal Free shall:
 - 12.4.1 without prejudice to clause 12.10, provide full details to the Authority of any Royal Free Background IPR or Third Party IPR which are an integral part of any element of Project Specific IPR; and
 - 12.4.2 execute all such assignments as are required to ensure that any rights in the Project Specific IPR are properly transferred to the Authority.
- 12.5 Royal Free hereby grants to the Authority a perpetual, fully paid-up, royalty-free, sub-licensable through multiple tiers, non-exclusive licence to use Royal Free Background IPR for any purpose relating to (a) the Project or (b) the Results, or for any purpose relating to the exercise of the Authority's (or any other Central Government Body's) business or function.
- 12.6 The Authority may sub-license the rights granted under clause 12.5 to a third Party, provided that the sub-licence is on terms no broader than those granted to the Authority.
- 12.7 The Authority may assign, novate or otherwise transfer its rights and obligations under the licences granted pursuant to clause 12.5 to:
 - 12.7.1 a Central Government Body; or
 - 12.7.2 to any body (including any private sector body) which performs or carries on any of the functions and/or activities that previously had been performed and/or carried on by the Authority.
- 12.8 Any change in the legal status of the Authority which means that it ceases to be a Central Government Body shall not affect the validity of any licence granted in clause 12.5. If the Authority ceases to be a Central Government Body, the successor body to the Authority shall still be entitled to the benefit of the licence granted in clause 12.5.
- 12.9 If a licence granted in clause 12.5 is novated under clause 12.7 or there is a change of the Authority's status pursuant to clause 12.8, the rights acquired on that novation or change of status shall not extend beyond those previously enjoyed by the Authority.
- 12.10 Other than Third Party IPR already disclosed to the Authority in accordance with Clause 12.4.1, Royal Free shall not use any Third Party IPR unless it has in either:

- 12.10.1 first procured that the owner or an authorised licensor of the relevant Third Party IPR has granted a direct licence to the Authority on a royalty-free basis and on terms no less favourable to the Authority than those set out in clauses 12.5, 12.6 and 12.7; or
 - 12.10.2 complied with the provisions of clause 12.11.
- 12.11 If Royal Free cannot obtain for the Authority a licence in respect of any Third Party IPR in accordance with the licence terms set out in clause 12.10, Royal Free shall:
 - 12.11.1 notify the Authority in writing giving details of what licence terms can be obtained from the relevant third Party and whether there are alternative providers which Royal Free could seek to use; and
 - 12.11.2 use the relevant Third Party IPR only if the Authority has first approved in writing the terms of the licence from the relevant third party.
- 12.12 Should Royal Free become aware at any time, including after termination, that the Project Specific IPR contain any Intellectual Property Rights for which the Authority does not have a suitable licence, then Royal Free must notify the Authority within ten (10) days of what those rights are and which parts of the Project Specific IPR they are found in.
- 12.13 For the avoidance of doubt, the termination or expiry of this Agreement shall not of itself result in any termination of any of the licences granted by Royal Free or relevant third party pursuant to or as contemplated by this clause 12.
- 12.14 The Authority hereby grants to Royal Free a royalty-free, non-exclusive, non-transferable licence to use the Authority Background IPR and the Project Specific IPR solely to the extent necessary for performing its obligations under and in accordance with this Agreement, including (but not limited to) the right to grant sub-licences provided that:
 - 12.14.1 any relevant sub-licensee has entered into a confidentiality undertaking with Royal Free with respect to such Authority Background IPR and Project Specific IPR on the same terms as set out in clause 10; and
 - 12.14.2 Royal Free shall not, without the Authority's prior written consent, use the licensed materials for any other purpose or for the benefit of any person other than the Authority.
- 12.15 In the event of the termination or expiry of this Agreement, the licence granted pursuant to clause 12.14 and any sub-licence granted by Royal Free in accordance with clause 12.14 shall terminate automatically on the date of such termination or expiry and Royal Free shall:
 - 12.15.1 immediately cease all use of the Authority Background IPR and any Results (as the case may be);
 - 12.15.2 at the discretion of the Authority, return or destroy documents and other tangible materials that contain any of the Authority Background IPR and the Results, provided that if the Authority has not made an election within 6 months of the termination of the licence, Royal Free may destroy the documents and other tangible materials that contain any of the Authority Background IPR and the Results (as the case may be); and
 - 12.15.3 ensure, so far as reasonably practicable, that any Authority Background IPR and Results that are held in electronic, digital or other machine-readable form ceases to be readily accessible from any Royal Free computer, word processor, voicemail system or any other Royal Free device containing such Authority Background IPR and/or Results.

13. **FREEDOM OF INFORMATION ACT**

13.1 Each Party acknowledges that the other Party is subject to the requirements of the FOIA and the EIRs. Each Party shall:

13.1.1 provide all necessary assistance and cooperation as reasonably requested by the other Party to enable it to comply with its obligations under the FOIA and EIRs;

13.1.2 transfer to the other Party all Requests for Information relating to this Agreement that it receives as soon as practicable and in any event within 2 Business Days of receipt;

13.1.3 provide the other Party with a copy of all Information belonging to that Party requested in the Request for Information which is in its possession or control in the form that the requesting Party reasonably requires within 5 Business Days (or such other period as the other Party may reasonably specify) of the request for such Information; and

13.1.4 not respond directly to a Request for Information unless authorised in writing to do so by the disclosing Party.

13.2 Each Party acknowledges that the other Party may be required under the FOIA and EIRs to disclose Information without consulting or obtaining consent from the other Party. Each Party shall take all reasonable steps to notify the other Party of a Request for Information (in accordance with the Cabinet Office's Freedom of Information Code of Practice issued under section 45 of the FOIA) to the extent that it is permissible and reasonably practical for it to do so but (notwithstanding any other provision in this Agreement) the disclosing Party shall be responsible for determining in its absolute discretion whether any Commercially Sensitive Information and/or any other information is exempt from disclosure in accordance with the FOIA and/or the EIRs.

13.3 Notwithstanding any other term of this Agreement, each Party consents to the publication of this Agreement in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA and EIRs.

13.4 Each Party shall, prior to publication, consult with the other Party on the manner and format of publication.

14. **ANTI-BRIBERY**

14.1 For the purposes of this clause 14 the expressions "**adequate procedures**" and "**associated with**" shall be construed in accordance with the Bribery Act 2010 and guidance published under it.

14.2 Each Party shall ensure that it and each person referred to in clauses 14.2.1 to 14.2.3 (inclusive) does not, by any act or omission, place the other Party in breach of any Bribery Laws. Each Party shall comply with all applicable Bribery Laws in connection with the performance of the Services and this Agreement, ensure that it has in place adequate procedures to prevent any breach of this clause 14 and ensure that:

14.2.1 all of its personnel and all direct and indirect subcontractors, suppliers, agents and other intermediaries of it;

14.2.2 all others associated with it; and

14.2.3 each person employed by or acting for or on behalf of any of those persons referred to in clauses 14.2.1 and/or 14.2.2,

involved in connection with this Agreement, so comply.

14.3 Without limitation to clause 14.2, each Party shall not in connection with the performance of the Services and/or this Agreement make or receive any bribe (which term shall be construed in accordance with the Bribery Act 2010) or other improper payment or advantage, or allow any such to be made or received on its behalf, either in the United Kingdom or elsewhere, and will implement and maintain adequate procedures to ensure that such bribes or improper payments or advantages are not made or received directly or indirectly on its behalf.

14.4 A Party shall immediately notify the other as soon as it becomes aware of a breach of any of the requirements in this clause 14.

15. **MODERN SLAVERY**

15.1 Each Party undertakes, warrants and represents that:

15.1.1 neither it nor any of its officers, employees, agents or subcontractors has:

- (a) committed an offence under the Modern Slavery Act 2015 (an "**MSA Offence**"); or
- (b) been notified that it is subject to an investigation relating to an alleged MSA Offence or prosecution under the Modern Slavery Act 2015; or
- (c) is aware of any circumstances within its supply chain that could give rise to an investigation relating to an alleged MSA Offence or prosecution under the Modern Slavery Act 2015;

15.1.2 it shall comply with the Modern Slavery Act;

15.1.3 it shall notify the other Party immediately in writing if it becomes aware or has reason to believe that it, or any of its officers, employees, agents or subcontractors have breached or potentially breached any of its obligations under clause 15. Such notice to set out full details of the circumstances concerning the breach or potential breach of the breaching Party's obligations.

16. **DATA PROTECTION**

16.1 Each Party agrees that, in the performance of their respective obligations under this Agreement, it shall comply with the provisions of Schedule 6.

17. **AUDIT**

17.1 Royal Free shall keep and maintain until six years after termination or expiry of this Agreement, or as long a period as may be agreed between the Parties, full and accurate records of this Agreement including:

17.1.1 the Services provided under it;

17.1.2 all expenditure reimbursed by the Authority; and

17.1.3 all payments made by the Authority.

17.2 Royal Free shall on request afford the Authority or the Authority's representatives such access to those records as may be reasonably required in connection with this Agreement.

18. **EQUALITY AND DIVERSITY**

18.1 Royal Free shall (and shall procure that the Royal Free Personnel shall):

18.1.1 perform its obligations under this Agreement (including those in relation to the Services) in accordance with:

- (a) all applicable equality law (whether in relation to race, sex, gender reassignment, age, disability, sexual orientation, religion or belief, pregnancy, maternity or otherwise);
- (b) the Authority's equality and diversity policy as provided to Royal Free from time to time; and
- (c) any other requirements and instructions which the Authority reasonably imposes in connection with any equality obligations imposed on the Authority at any time under Applicable Law; and

18.1.2 take all necessary steps, and inform the Authority of the steps taken, to prevent unlawful discrimination designated as such by any court or tribunal, or the Equality and Human Rights Commission or (any successor organisation); and

18.1.3 at all times comply with the provisions of the Human Rights Act 1998 in the performance of this Agreement. Royal Free shall also undertake, or refrain from undertaking, such acts as the Authority requests so as to enable the Authority to comply with its obligations under the Human Rights Act 1998.

19. **LIMITATION OF LIABILITY**

19.1 The extent of each Party's liability under or in connection with this Agreement (regardless of whether such liability arises in tort, contract or in any other way and whether or not caused by negligence or misrepresentation) shall be as set out in this clause 19.

19.2 Subject to clauses 19.3, 19.4 and 19.6, each Party's aggregate liability to the other Party in respect of all claims arising out of or in connection with this Agreement (whether for breach of contract, in negligence or any other tort, under statute or otherwise) shall be limited to a sum equal to 100% of the Service Charges paid or payable by the Authority under this Agreement.

19.3 Subject to clause 19.6, neither Party shall be liable for any consequential, indirect or special loss.

19.4 Subject to clause 19.6, neither Party shall be liable for any of the following (whether direct or indirect):

19.4.1 loss of profit;

19.4.2 loss of or corruption to data;

19.4.3 loss of use;

19.4.4 loss of production;

19.4.5 loss of contract;

19.4.6 loss of commercial opportunity;

19.4.7 loss of savings, discount or rebate (whether actual or anticipated);

19.4.8 harm to reputation or loss of goodwill.

19.5 Except as expressly stated in this Agreement, and subject to clause 19.6, all warranties and conditions whether express or implied by statute, common law or otherwise are excluded to the extent permitted by law.

19.6 Notwithstanding any other provision of this Agreement, the liability of the Parties shall not be limited in any way in respect of the following:

19.6.1 death or personal injury caused by negligence;

19.6.2 fraud or fraudulent misrepresentation;

19.6.3 any other losses which cannot be excluded or limited by Applicable Law.

19.7 In the event of:

19.7.1 any claim or proceeding in respect of personal injury being made or brought against the Authority by a subject of the Study; and

19.7.2 that claim or proceeding being as a result of Royal Free's negligent performance of the Services or of Royal Free's obligations under this Agreement,

Royal Free shall indemnify the Authority against any claims, proceedings and related costs, expenses, losses and damages arising from Royal Free's negligent performance of the Services or of Royal Free's obligations under this Agreement, save to the extent that they were caused, or contributed to, by the negligence, wrongful acts, omissions, or breach of statutory duty of the Authority.

19.8 For the avoidance of doubt, the Parties acknowledge that they are the recipients of other indemnities under the Project Collaboration Agreement and other Service Agreements relating to the Study and that there shall be no double counting or claiming of losses across the various agreements.

20. **INSURANCE**

Royal Free must put in place and maintain in force appropriate indemnity arrangements in respect of its obligations under this Agreement, including employer's liability, clinical negligence where the provision or non-provision of the Services may result in a clinical negligence claim, public liability and professional negligence insurance. Upon the Authority's request Royal Free shall provide documentary evidence that the indemnity arrangements are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.

21. **TERMINATION**

21.1 Either Party may terminate this Agreement at any time by giving notice in writing to the other Party if:

21.1.1 the other Party commits a material breach of this Agreement and such breach is not remediable; or

21.1.2 the other Party commits a material breach of this Agreement which is not remedied within 14 days of receiving written notice of such breach.

21.2 Either Party may terminate this Agreement at any time by giving notice in writing to the other Party if that other Party:

- 21.2.1 in the case of Royal Free, stops carrying on all or a significant part of its business, or indicates in any way that it intends to do so;
 - 21.2.2 is unable to pay its debts either within the meaning of section 123 of the Insolvency Act 1986 or if the non-defaulting Party reasonably believes that to be the case;
 - 21.2.3 becomes the subject of a company voluntary arrangement under the Insolvency Act 1986;
 - 21.2.4 has a receiver, manager, administrator or administrative receiver appointed over all or any part of its undertaking, assets or income;
 - 21.2.5 has a resolution passed for its winding up;
 - 21.2.6 has a petition presented to any court for its winding up or an application is made for an administration order, or any winding-up or administration order is made against it;
 - 21.2.7 is subject to any events or circumstances analogous to those in clauses 21.2.1 to 21.2.6 in any jurisdiction;
 - 21.2.8 takes any steps in anticipation of, or has no realistic prospect of avoiding, any of the events or procedures described in clauses 21.2.1 to 21.2.7 including for the avoidance of doubt, but not limited to, giving notice for the convening of any meeting of creditors, issuing an application at court or filing any notice at court, receiving any demand for repayment of lending facilities, or passing any board resolution authorising any steps to be taken to enter into an insolvency process.
- 21.3 If a Party becomes aware that any event has occurred, or circumstances exist, which may entitle the other Party to terminate this Agreement under this clause 21, it shall immediately notify the other Party in writing.
- 21.4 Termination or expiry of this Agreement will not affect any accrued rights and liabilities of either Party at any time up to the date of termination.
- 21.5 On termination of this Agreement, Royal Free shall ensure that all data relating to the Project including but not limited to records of all Results and all research, development and other work carried out in connection with the Project are held to the Authority's order and promptly returned directly to the Authority or made available for collection by or on behalf of the Authority.
- 22. DISPUTE RESOLUTION**
- Any dispute arising between the Parties out of or in connection with this Agreement shall be dealt with in accordance with the Dispute Resolution Procedure in Schedule 8 of the Project Collaboration Agreement.
- 23. FORCE MAJEURE**
- 23.1 In this clause, Force Majeure means an event or sequence of events beyond a Party's reasonable control preventing or delaying it from performing its obligations under this Agreement. Inability to pay is not Force Majeure.
- 23.2 A Party shall not be liable if delayed in or prevented from performing its obligations under this Agreement due to Force Majeure, provided that it:
- 23.2.1 promptly notifies the other of the Force Majeure event and its expected duration; and

23.2.2 uses reasonable endeavours to minimise the effects of that event.

23.3 If, due to Force Majeure, Royal Free:

23.3.1 is or is likely to be unable to perform a material obligation; or

23.3.2 is or is likely to be delayed in or prevented from performing its obligations for a total of more than ten (10) Business Days,

the Authority may terminate this Agreement on not less than four weeks' written notice.

24. GENERAL

24.1 Conflicts within Agreement

24.1.1 In the event of any conflict or inconsistency between this Agreement and the provisions of any other agreement between the Parties, the following descending order of priority applies:

- (a) the Project Collaboration Agreement;
- (b) the provisions of this Agreement;
- (c) any other agreement between the Project Partners.

24.1.2 Subject to the above order of priority between documents, later versions of documents shall prevail over earlier ones if there is any conflict or inconsistency between them.

24.2 Entire Agreement

The Parties agree that this Agreement and the Project Collaboration Agreement constitute the entire agreement between them and supersedes all previous agreements, understandings and arrangements between them, whether in writing or oral in respect of its subject matter.

24.3 Amendment

No variation or amendment of this Agreement will be effective unless it is made in writing and signed by each Party's representative.

24.4 Assignment

The Authority may assign or otherwise transfer any rights or obligations under this Agreement without the prior written consent of the other Party.

24.5 Waiver

No failure or delay on the part of any Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.

24.6 No Agency

None of the Parties shall act or describe itself as the agent of any of the other Parties, nor shall it make or represent that it has authority to make any commitments on any of the others' behalf.

24.7 Interpretation

In this Agreement:-

- 24.7.1 the headings are used for convenience only and shall not affect its interpretation; and
- 24.7.2 references to persons shall include incorporated and unincorporated persons; references to the singular include the plural and vice versa; and references to the masculine include the feminine.

24.8 Notices

- 24.8.1 Any notice to be given under this Agreement shall be in writing and shall be sent by first class mail to the address of the relevant Party set out at the head of this Agreement, or to the relevant email address set out below, or such other address or email address as that Party may from time to time notify to the other Party in accordance with this clause 24.8.

- 24.8.2 The contact names and email addresses of each of the Parties are as follows:-

Authority – The Secretary of State [REDACTED]

Royal Free – [REDACTED]

- 24.8.3 Notices sent as above shall be deemed to have been received three Business Days after the day of posting, or on delivery to the recipient's email address.

24.9 Severance

If any provision of this Agreement (or part of any provision) is or becomes illegal, invalid or unenforceable, the legality, validity and enforceability of any other provision of this Agreement shall not be affected and shall remain in full force and effect.

24.10 Counterparts

- 24.10.1 This Agreement may be signed in any number of separate counterparts, each of which when signed and dated shall be an original, and such counterparts taken together shall constitute one and the same agreement.
- 24.10.2 Each Party may evidence their signature of this Agreement by transmitting a signed signature page of this Agreement in PDF format together with the final version of this Agreement in PDF or Word format, which shall constitute an original signed counterpart of this Agreement. Each Party adopting this method of signing shall, following circulation, provide the original, hard copy signed signature page to the other Parties as soon as reasonably practicable.

24.11 Law and Jurisdiction

The validity, construction and performance of this Agreement shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the Parties hereby submit, except that a Party may seek an interim injunction in any court of competent jurisdiction.

24.12 Further action

Each Party agrees to execute, acknowledge and deliver such further instruments, and do all further similar acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

AGREED by the Parties through their authorised signatories:-

SIGNED for and on behalf of **DEPARTMENT SIGNED** for and on behalf of **ROYAL FREE FOR BUSINESS, ENERGY AND INDUSTRIAL LONDON NHS FOUNDATION TRUST:**
STRATEGY:

Name 

Name 

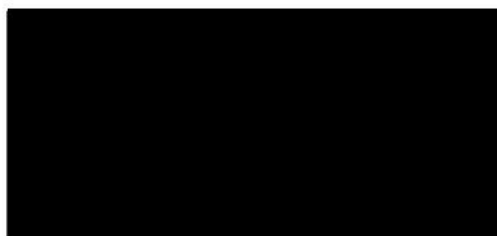
Position Director General, Vaccine Task Force

Position Group Chief Finance &
Compliance Officer

Signature



Signature



SCHEDULE 1

CATERING SERVICES

1. INTERPRETATION

- 1.1 Capitalised terms used in this Schedule are as defined in the relevant SOPs and/or NHS handbooks unless expressed otherwise herein.

2. AUTHORITY

- 2.1 For all operational changes decisions involving additional cost and / or a change in the service described below, The Commercial Finance Director is the authorised Trust representative.

3. SCOPE OF SERVICES AND PERFORMANCE STANDARDS

- 3.1 Royal Free will offer a dining service as set out in this paragraph 3:

3.1.1 For Patients

Beverages 07.00-22.00 On demand, but offering a minimum of 7 brewed tea and coffee. per day to include juices, water.

Breakfast 07.30 – 10.00 Traditional cooked breakfast to include vegetarian options

Continental breakfast

Patient orders for breakfast will be taken from 7.30AM

Lunch Service 12.00-14.00 Minimum of three options (reflective of a quality restaurant table d'hôte service offer) comprising 3 hot or cold starters, 3 main courses, 2 desserts fruit can be provided as alternative to dessert.

Patient orders for lunch will be taken from 9.30AM to 11.00 AM

Afternoon Tea 15.30-16.30 Selection of bakery goods beverage selection (from allowance of 7)

Evening Meal 18.30 – 20.00 Minimum of three options (reflective of a comprising 3 hot or cold starters, 3 main quality restaurant table d'hôte service offer) courses to include one vegetarian option and vegetable accompaniments and three hot or cold dessert choices. Fresh fruit to be provided as alternative to dessert.

3.1.2 Other service criteria

Meal entitlement The agreed fixed price for patient food includes allowance for:

- o Breakfast either hot or cold
- o Three course lunch
- o Three course dinner

- o Up to seven hot beverages per day
- o Up to two x 750 ml bottles of mineral water

Menu Fixed menus will be displayed within the patients rooms in an accessible position.

Daily menus will be presented to the patient on the evening before and placed in the back of the fixed menu.

Any new menus will be mutually agreed before printing and dissemination.

A 21 day menu cycle shall be maintained

A minimum of 90% of the agreed choice for breakfast, lunch, dinner and All Day will be available daily.

Timing of meals Upon taking an order patients may specify the time they wish to dine and should be served within plus and minus 10 minutes of this time.

If a time is not specified then all on demand orders will be served within 45 minutes of order placement

The team will further ensure that patients' trays are cleared within 15 minutes or meal consumption.

Presentation of trays All lunch and dinner trays will be accompanied by the correct cutlery, crockery, condiments, linen napkin and tray cloth.

All breakfast and beverage trays will be accompanied by the above but with a good quality disposable napkin.

4. **SERVICE CHARGES**

4.1 These costs will be charged at costs and volume at [REDACTED] per patient per day.

SCHEDULE 2

HARD AND SOFT FM SERVICES

1. INTERPRETATION

- 1.1 Capitalised terms used in this Schedule are as defined in the relevant SOPs and/or NHS handbooks unless expressed otherwise herein.

2. DEFINITIONS

- 2.1 In this Schedule 2 the following definitions shall apply:

"Access Times"	means the times within which Planned Maintenance activities may be carried out;
"Capital Equipment"	<p>means equipment that is built in to the Premises, specifically for the delivery of the Services, including any items that are permanently plumbed in or wired in to the Premises;</p> <p>N.B. Capital equipment for trust retained in-house services will already be incorporated within the definition of Premises;</p>
"Condition B"	means in respect of the physical condition of the Premises, all the components are sound, operationally safe and exhibit only minor deterioration. Where components fall short of this condition and rectification is planned to occur within 6 months, the component shall be deemed to be Condition B provided that at all times the components shall be of a sufficient condition so as not to present risk of injury or have any material effect on the Recipient's ability to operate as contemplated by this Agreement;
"Contract Month"	means each month of this Agreement;
"Emergency"	means any Fault felt to be life threatening or serious enough to cause significant damage or disruption. Any time parameter ascribed to this category will be measured from the time of notification to the Helpdesk;
"Estate Services"	means the Services to be carried out pursuant to this specific service specification;
"Fault"	means a failure of the Premises or a component part;
"Hard and Soft FM Services"	means the Hard FM Services and the Soft FM Services;
"Hard FM Services"	means the hard facilities management services detailed in Appendix 1;
"Helpdesk"	means a list of resources specifically telephone numbers to enable the Recipient to log and report Faults to Royal Free both in and outside of Normal Working Hours;

"Maintenance"	means any maintenance, upkeep, repair, replacement or renewal of any part of the Premises in accordance with Condition B;
"Mechanical and Electrical Services"	means the services (including related plant listed in Annex C.);
"Normal Working Hours"	means Monday to Friday 8am to 5pm;
"PAT"	means Portable Appliance Testing;
"Permits to Work"	means the authority given by Royal Free, or in certain circumstances by the Recipient, to undertake safe systems of work which may cause risk to Royal Free or Recipients employees or disruption to the Recipients activities;
"Routine"	means any Fault that is not seen as immediately detrimental and not causing significant operational problems or any ad hoc service request that is not seen as immediately detrimental and not causing significant operational problems if not attended to. Any time parameter ascribed to this category will be measured from the time of notification to the Helpdesk;
"Soft FM Services"	means the soft facilities management services detailed in Appendix 2;
"Specialist Services"	means the services (including related plant) set out in Annex B to Appendix 1; and
"Urgent"	means any Fault that shall cause operational problems if not attended to quickly, or which may develop into an Emergency if not remedied which requires attendance quickly to avoid operational problems or an Emergency if not remedied. Any time parameter ascribed to this category will be measured from the time of notification to the Helpdesk.

3. SCOPE OF SERVICES AND PERFORMANCE STANDARDS

- 3.1 Royal Free shall provide the Hard and Soft FM Services to the Recipient in accordance with this Schedule 2 and/or as otherwise reasonably directed by the Recipient.
- 3.2 Royal Free shall:
 - 3.2.1 accept tasks via the Helpdesk meeting the defined interpretation of category Emergency, Urgent or Routine.
 - 3.2.2 perform the Services with reasonable care and skill and in accordance with generally recognised commercial practices and standards in the industry for similar services including NHS requirements, where applicable;
 - 3.2.3 allocate sufficient resources to ensure the performance of the Services and the Parties will co-operate in all matters relating to the Services
 - 3.2.4 ensure that the Services conform with all descriptions and specifications provided to Royal Free by the Recipient and where the provider has been given the opportunity to provide a specific cost where this is above normal service delivery;
 - 3.2.5 ensure that the Services will be provided in accordance with statutory compliance in force at the time of this Agreement; and

- 3.2.6 observe and procure that its relevant personnel shall observe, all health and safety rules and regulations and any other security requirements that apply at the Recipient's Premises.
- 3.3 The Recipient shall:
 - 3.3.1 for all Routine maintenance requests the Recipient shall use the internet reporting system to report Service Failures, obtain job codes and follow up work requests;
 - 3.3.2 report all Faults to the helpdesk as they occur;
 - 3.3.3 In Emergency situations and out of hours the Recipient shall access response through the telephone/bleep systems advised by Royal Free;
 - 3.3.4 ensure access is available during Normal Working Hours where reasonable notice of 5 days is given in order that Royal Free can provide service;
 - 3.3.5 On commencement of the agreement the Recipient will provide to Royal Free a procedure for Emergency access; and
 - 3.3.6 where advised any plant is uneconomical to repair make arrangements to procure and install and commission a substitute.
- 3.4 Upon the completion of this Agreement, Royal Free and Recipient shall each appoint Royal Free's Recipient's Services Manager and the Recipient's Services Manager respectively and provide details of the identity of such person to the other Party.
- 3.5 Royal Free's Recipient's Services Manager and the Recipient's Services Manager shall meet at least once every month to discuss matters relating to the Services. Without prejudice to clause 9, if either party wishes to change the scope or execution of the Services, they shall submit details of the request for change to the other in writing and the parties shall meet and discuss in good faith the said request (but with no obligation to accept the same).
- 4. **SERVICE CHARGES**
- 5. In consideration of the provision of the Hard and Soft FM Services (and rental costs for the Premises), the Authority shall pay the Service Charges as detailed in Appendix 3.
- 5.1 Royal Free shall issue its invoice in respect of the Hard and Soft FM Services [REDACTED]
- 5.2 Royal Free shall refund to the Authority any amounts paid in advance for Hard and Soft FM Services not delivered.

Appendix 1

HARD FM SERVICES

1. OVERVIEW

- 1.1 Royal Free shall provide a Maintenance Service as set out in Annexes A-D
- 1.2 The Estates Service shall be provided between the hours of 8am to 4:30pm Monday to Friday with provision for an emergency response 24 hours per day, 365(6) days per year.
- 1.3 The Maintenance Service applies to all areas of the Premises.

2. KEY OBJECTIVES

- 2.1 Royal Free shall:
 - 2.1.1 provide a timely and proactive service that ensures the integrity of the building fabric, building services, public health and utility systems, furniture and equipment which comprises the Premises;
 - 2.1.2 minimise disruption to the Recipients operations by maintaining the Premises to ensure reactive responses are limited; and
 - 2.1.3 ensure that the Premises does not cause or create any hazard to the local environment and/or any person as a consequence of the works under the control of Royal Free.

3. SCOPE OF SERVICES AND PERFORMANCE STANDARDS

- 3.1 Royal Free shall comply with all requirements set out in this Service Schedule including the Performance Standards detailed in Annex A to this Appendix 1.
- 3.2 Royal Free shall provide, unless otherwise stated, all requisite plant, equipment, apparatus and agreed list of consumable items required for the proper execution of all work which Royal Free is required to carry out under this Service Schedule; including without limitation scaffolding, craneage, tackle, machinery, tools or other appliances and everything else necessary for the work, and shall be responsible for their conveyance, use, subsequent removal, making good and cleaning.
- 3.3 Royal Free shall take full regard of the requirements set out in Annex C.
- 3.4 Royal Free shall ensure that following any Maintenance, the area is left in a condition that enables the Recipient to undertake its activities efficiently.

4. SPECIFIC REQUIREMENTS

5. *Reporting*

- 4.1 At the commencement of the contract, Royal Free shall provide to the Recipient for agreement a list of reports relating to the Premises. Once agreed Royal Free will issue a copy of the reports to the Recipient's Services Manager.
- 4.2 Working to Royal Free standard operating procedures and notifying a designated individual weekly of any Permits to Work.

6. *Programmed Maintenance*

- 4.3 Royal Free shall update its programme of Maintenance so all areas are included including Lab and [REDACTED]. Royal Free shall provide for the Premises and Equipment as listed in Annex D an annual maintenance schedule to the Recipient in sufficient detail to enable the Recipient to plan to minimise disruption to clinical activities ("**Schedule of Programmed Maintenance**"). The standard to be achieved is Condition B.
- 4.4 Royal Free shall provide a quarterly update to the Schedule of Programmed Maintenance.
- 4.5 Each Contract Month Royal Free shall provide a monthly report within 10 working days of month end to the Recipient providing details of:
- 4.5.1 all Maintenance (planned or otherwise) undertaken in that month;
 - 4.5.2 testing (statutory, PAT, insurance company and legionella) carried out;
 - 4.5.3 the forthcoming five weeks' work and including the following information as a minimum:
 - (a) location of the work to be undertaken clearly identifying activities which are anticipated to cause disruption to the Recipient's operations;
 - (b) time period (within 3 days) when the work is to be undertaken;
 - (c) sub-contractors to be used (named individual(s)); and
 - (d) any Permits to Work needed,
- 4.6 Royal Free will carry out all required PAT testing in accordance with Royal Free standards for all equipment for PAT testing to be used on the Premises prior to the Commencement Date.
- 4.7 The Recipient, as required under sections 9 & 10 of the Management of Health & Safety at Work Regulations 1999, will meet its obligation to provide Royal Free with sufficient hazard and safety information to enable the production of RAMS. Royal Free shall maintain comprehensive operational method statements for planned and reactive activities incorporating risk assessments.
- 4.8 Royal Free shall conduct an annual review of these operational method statements.
- 4.9 No works shall be carried out on the existing infrastructure / estate without the express permission of the Royal Free London Estates Team. All works carried out will be done so under the existing permit to work scheme.
- 4.10 Royal Free shall ensure that programmed Maintenance accords with their operational method statements.
- 4.11 Royal Free shall endeavour to carry out and complete Programmed Maintenance at the agreed scheduled time and to a standard that maintains Condition B.
- 4.12 Royal Free shall ensure no programmed Maintenance is carried out in areas outside the Normal Working Hours without prior written consent from Royal Free's Representative. In the event that a department or area is in use by the Trust during the Access Times agreed Royal Free may make a claim for consequential losses incurred.

Reactive repairs & Maintenance

- 4.13 All elements of the Premises shall comply with Condition B. Where Faults occur in the Premises, Royal Free shall make safe and rectify such Faults within the Make Safe and Rectification Times (as set out in section 4.14). In certain circumstances Royal Free may

need to provide a Temporary Repair, due to the need for specialist materials or personnel that are not, and cannot reasonably be expected to be, immediately available at the Premises. In these instances the Recipient agrees Royal Free may provide Temporary Repair of a nature, and for a duration, that is required to make a permanent repair.

4.14 **Make Safe and Rectification Times for Faults:**

Category of Fault	Response Time
Emergency Faults	within 1 hour
Urgent Faults	within 1 working day
Routine Faults	within 5 working days
For Temporary Repair	Duration as required to make a permanent repair.

- 4.15 Reactive repairs undertaken by Royal Free accord with their operational task based method statements.

Statutory testing

- 4.16 Royal Free shall undertake all actions arising from planned tests, where this relates to Maintenance and undertakes to advise the Recipient of all other actions outside of the specified service.

- 4.17 Royal Free and the Recipient shall ensure all new plant and equipment is commissioned in accordance with manufacturer's instructions. Where this is to be maintained by Royal Free the Recipient shall ensure such commissioning is to the satisfaction of Royal Free.

Permits to Work

- 4.18 Royal Free shall apply a Permit to Work scheme where any work may affect the Recipients operations, and ensure that any such Permit to Work are adhered to.

Minor Works

- 4.19 Royal Free shall, where they have capacity to do so, undertake additional requests for work on a variation basis. For the avoidance of doubt, the cost of this service shall be dealt with in accordance with the Variation Procedure. The Recipient will notify Royal Free of any alterations to the Premises as outlined in their Lease obligations under the terms of their Lease.

Fire safety systems & procedures

- 4.20 The Recipient shall retain responsibility under RRO 2005 for the fire safety systems, joint policy and will require Royal Free to maintain fire safety systems on their behalf. Royal Free shall collaborate with the Recipient within timescales set out by NHS Firecode, or, where these are not stated, within reasonable periods of time, to agree all emergency procedures and contingency plans as these shall relate to the provision of any aspect of Royal Free's obligations and responsibilities as set out in the Agreement.

- 4.21 Royal Free shall ensure that all Royal Free staff are regularly given fire safety lectures in compliance with HTM 05-03. The Recipient shall ensure that all Recipient staff are regularly given fire training and maintain a schedule of attendance.

- 4.22 Royal Free shall provide to the Recipient an annual written report in the agreed format, quality and standard, providing the following information on the Premises:
- 4.22.1 confirmation that the Premises, including, but not limited to, fire compartmentalisation design, provision of escape routes and provision of fire fighting equipment and systems, complies with the minimum requirements of NHS Firecode;
 - 4.22.2 confirmation that procedures for which Royal Free is responsible, including emergency procedures and contingency plans comply with the minimum requirements of NHS Firecode; and
 - 4.22.3 the Recipient shall undertake a condition survey before taking occupation of the Premises. Such survey shall be agreed between both the Recipient and Royal Free. The Recipient agrees to hand back the above areas to the same condition/standard as that which is provided and noted through the condition survey upon completion of this Agreement provided that, for the avoidance of doubt, the Recipient will not be liable for any failure of the Premises to comply with such condition report to the extent that such failure has arisen as a result of Royal Free's failure to provide the Services in accordance with this Agreement.

Providing information

- 4.23 Royal Free shall prepare and supply all information reasonably required by any person, firm, governmental authority or other body to whom the Recipient is obliged to present information at any time in relation to the performance of the Estates Service.
- 4.24 Royal Free shall record all complaints and respond to any complaints as agreed with the Recipient.
- 4.25 Royal Free shall make available to the Recipient accurate record information. The extent of this information, if held by Royal Free, shall include but not be limited to the following:
- 4.25.1 physical characteristics of the Premises including but not limited to:
 - (a) the description and address of the Premises;
 - (b) all area and buildings volume data;
 - (c) condition surveys; and
 - (d) up to date CAD / hard copy drawings for structural, mechanical and electrical elements; and
 - 4.25.2 test certificates and appropriate documentation and records (in particular those relating to any aspects of safety or statutory compliance) shall be maintained accurately, shall be updated appropriately and shall be available for inspection by the Trust or any other relevant party.

Lifts

- 4.26 During the period of occupation, Royal Free will be undertaking a lift refurbishment programme which will render 2 out of the 6 main lifts throughout the tower out of action. Alternative lifts are being made available and the communications around this programme will be made available to the Recipient as and when required. It is not envisaged that these works will have a detrimental impact on service provision throughout the tower. Royal Free will work with HVIVO to ensure that these works have no impact on the Project.

5. **EXCLUSIONS**

5.1 Royal Free is not required to undertake work related to:

- 5.1.1 the maintenance of any equipment brought to the Premises by HVIVO;
- 5.1.2 the maintenance of external areas;
- 5.1.3 the maintenance of any IT hardware, software, or infrastructure including wiring; or
- 5.1.4 standalone fume and safety cupboards.

ANNEX A – SPECIFIC REQUIREMENTS

7. A.1 BUILDING

Element	Standard
Building Fabric External including: <ul style="list-style-type: none"> ▪ external walls, ▪ roofs, chimneys, gutters and rainwater systems, ▪ glazing, ▪ fire escapes, ▪ walkways, safety barriers, ▪ balconies, ▪ eaves, ▪ rendering, ▪ lighting conductors. 	<ul style="list-style-type: none"> ▪ All elements of building fabric, finishes, furniture and Equipment or a services system component shall be functional, operational and satisfy the performance requirements as specified in Condition B ▪ Sound secure and weatherproof where appropriate ▪ Free from damp penetration or spalling ▪ Claddings, copings and parapets are structurally sound and secure ▪ free from areas capable of harbouring vermin and/or pests ▪ chimney stacks/flues are structurally sound and secure and flue is free from blockages/excess soot. ▪ Free from debris and moss growth
Building Fabric Internal including: <ul style="list-style-type: none"> ▪ substructure, ▪ superstructure, ▪ internal walls, ▪ partitions, ▪ ceilings. 	<ul style="list-style-type: none"> ▪ All elements of building fabric, finishes, furniture and Equipment or a services system component shall be functional, operational and satisfy the performance requirements as Condition B ▪ free from structural cracks and/or deflection ▪ free from damp and vermin ▪ free from undue damage and of reasonable appearance for location ▪ free from unsealed asbestos
Fixtures and Fittings including <ul style="list-style-type: none"> ▪ doors (external, internal and fire) ▪ windows and cills, ▪ hatches, ▪ vents, ▪ ironmongery, ▪ cupboards, ▪ railings, ▪ balustrades ▪ magnetic door holders 	<ul style="list-style-type: none"> ▪ operate as intended, in a safe way, without making undue noise and without including observable stains on hinges, locks, catches and handles, and without binding, rubbing or catching in any way; ▪ shall function as intended, and shall be free from all but minor surface blemishes and wear and tear ▪ luminescent strips, signs, notices, warning signs where appropriate are intact, legible and illuminated where appropriate; ▪ free from corrosion
Floor and Floor Coverings	<ul style="list-style-type: none"> ▪ The floor coverings are complete, according to their specification ▪ The floor covering is fully fixed to the floor so as not to cause a health and safety hazard; ▪ The floor/floor covering is free from tears, scoring, cracks or any other damage that is unsightly and/or could cause a health and safety hazard; ▪ Floor coverings/surfaces shall be maintained in such a way as to provide a suitable uniform surface (taking into account the pre-existing sub-surface ▪ allow adequate drainage where necessary; ▪ free from pests
Decorative Finishes <ul style="list-style-type: none"> ▪ including paintwork, fabric and special finishes applied to walls, ceilings, woodwork, metalwork, pipework and other visible elements. 	<ul style="list-style-type: none"> ▪ decorative finishes are complete according to their specification, ▪ free from all but minor surface blemishes or undue wear and tear; ▪ free from cracks, or any other surface degradation inconsistent with a building maintained in accordance with Good Industry Practice;

8. **A.2 ENERGY / UTILITY / INFRASTRUCTURE SERVICES**

Element	Requirement
<p>Energy / Utilities / Infrastructure Services This includes but is not limited to:</p> <ul style="list-style-type: none"> a) sanitation and drainage systems; b) water systems; c) electricity distribution system; d) gas distribution system e) HVAC 	<ul style="list-style-type: none"> ▪ Services should be free from leaks. ▪ Services should be maintained to deliver their specified capacity.

9. A.3 SPECIALIST SERVICES

Element	Requirement
Specialist Services (as defined in Annex B)	<ul style="list-style-type: none">▪ All Specialist Services shall function as intended, at the correct temperatures, quality and standards and flow rates without undue noise or vibration.▪ All pipework and fittings shall be fastened securely to their intended points of anchorage. There shall be no leaks of piped gases and/or liquids and/or solids.▪ All pipework and fittings to be clearly labelled to identify its service.

10. **A.4 MECHANICAL & ELECTRICAL SYSTEMS AS DEFINED IN ANNEX C**

Generators and emergency power supply	<ul style="list-style-type: none"> Standby power source shall be operational, secure and tested regularly Emergency lighting units shall comply with BS5299, be free from dust, operational and fully charged Batteries and battery rooms shall be adequately ventilated, free from acid leakage; batteries shall be topped up and fully charged Static inverters shall be in working order and not overheat during normal operational loading
Low voltage distribution system including distribution equipment and protective devices fuse switches, isolators, distribution boards, fuses, MCBs, ACB, ELCBs and RCD's, exposed distribution cables	<ul style="list-style-type: none"> Ratings shall be clearly marked Fuse elements or circuit breaker mechanisms in working order contacts and connections clean and mechanically tight no overheating during normal operating loads secure to authorised access only recording instruments operational where necessary cable joint boxes free from compound leaks marker and covering notices where necessary
High voltage distribution systems including distribution equipment, protective devices, isolators, distribution units, OCBs, ACBs and ELCBs	<ul style="list-style-type: none"> Ratings shall be clearly marked Fuse elements or circuit breaker mechanisms in working order Contacts and connections clean and mechanically tight No overheating during normal operating loads Secure to authorised access only Recording instruments operational where necessary Transformers are free from oil leaks Protective coatings are intact No signs of excessive heating Electric strength of oil satisfactory Cable joint boxes free from compound leaks Marker and covering notices where necessary
Hot & cold water systems	<ul style="list-style-type: none"> Deliver water at the temperatures and flow rates without undue noise and vibration. Taps, valves and other related fittings and fixtures function as intended. Pipework and fittings shall be fastened securely to their intended points of anchorage. There shall be no drips or leaks of water from pipework, taps, valves and/or fittings.
Heating, air conditioning and mechanical ventilation systems including boilers, calorifiers and heat exchangers, fume cupboards, humidifiers heaters, ductwork, mixing boxes and dampers coolers, inlet/outlet grilles refrigeration plant, cooling towers and other local ventilation systems.	<ul style="list-style-type: none"> All ventilation systems shall function as intended without undue noise or vibration; Air changes and ventilation levels as required; Ductwork, fittings and pipework shall be securely fastened to their intended points of anchorage; There shall be no leaks of water (or other heating/cooling medium) or air from ventilation systems; Secure to authorised access only; free from corrosion, erosion and organic growth; All pipework and fittings to be clearly labelled to identify its service.
Electrical power and other cabled systems including <ul style="list-style-type: none"> Lighting safety and alarm systems 	<ul style="list-style-type: none"> All electrical installations to comply with BS7671 or equivalent. Weatherproof where appropriate Function as intended without undue noise or vibration; Wiring, fittings, fixtures, controls and safety devices shall be properly housed and fastened securely to their intended point of anchorage and labelled. Lighting conductor should be complete, isolated and comply with

	BS6651 or equivalent <ul style="list-style-type: none"> ▪ MICC cable protective coatings intact ▪ Light emittance within design Lux levels
Public health and other drainage systems (including all sanitary ware and associated fittings)	<ul style="list-style-type: none"> ▪ Shall function as intended, without undue noise and vibration, ▪ Provide a safe and comfortable environment; ▪ All pipework and fittings fastened securely to their intended points of anchorage; ▪ There shall be no leakage of waste and/or foul water and/or rain water.
Fire fighting equipment	<ul style="list-style-type: none"> ▪ Fire extinguishers and other fire fighting equipment shall be maintained in accordance with BS 5306 Part 3 Code of Practice or equivalent. ▪ Sound, secure and fixed to their intended points of anchorage. ▪ Fully operational within manufacturer's recommendations. ▪ Hydrants, sprinklers and hoses shall be at correct operating pressure and capacity; ▪ Pipework shall be free from corrosion, leaks and drips ▪ Be of suitable type and quantity for the hazards present within their vicinity
Lifts	<ul style="list-style-type: none"> ▪ Shall function as intended without undue noise or vibration. ▪ Shall have a fully functioning control panel and phone ▪ No persons shall be trapped in a lift for more than 60 minutes.

ANNEX B - SPECIALIST SERVICES

1. The following are categorised as Specialist Services:
 - 1.1 pneumatic tube system;
 - 1.2 piped medical gases;
 - 1.3 compressors and vacuum systems;
 - 1.4 emergency power supply;
 - 1.5 emergency alarm systems and equipment;
 - 1.6 specialist fridge's and freezers;
 - 1.7 hospital fire safety system
 - 1.8 building management system;
 - 1.9 combined heat and power systems;
 - 1.10 water treatment plant (chlorine dioxide, copper / silver ionisation); and
 - 1.11 fixed fume cupboards supplied by central plants.

ANNEX C - MECHANICAL & ELECTRICAL SERVICES

1. The following are categorised as Mechanical & Electrical services:
 - 1.1 external lighting installation and illuminated signage;
 - 1.2 internal electrical power and lighting installations;
 - 1.3 emergency lighting systems;
 - 1.4 fire alarm systems;
 - 1.5 fixed and portable electrical appliances (where equipment is made available);
 - 1.6 lifts;
 - 1.7 temperature monitoring of the fridges in the lab;
 - 1.8 space heating systems;
 - 1.9 cooling systems (including chilled beams);
 - 1.10 air conditioning systems;
 - 1.11 portable and fixed fire extinguishing systems;
 - 1.12 electrical mains distribution system;
 - 1.13 emergency electrical generation plant and equipment;
 - 1.14 chilling plant and chilled water storage and distribution systems;
 - 1.15 thermal systems and distribution systems;
 - 1.16 heating plant, steam and hot water distribution systems;
 - 1.17 domestic hot water storage and distribution systems;
 - 1.18 central air handling plant;
 - 1.19 cold water storage and distribution systems;
 - 1.20 refrigeration equipment;
 - 1.21 cooling towers;
 - 1.22 fixed and portable first aid fire fighting systems other than automatic fire fighting systems under Annex C;
 - 1.23 mechanical and manual heating and ventilation systems;
 - 1.24 specialist climate control systems; and
 - 1.25 street and security lighting systems.

ANNEX D - EQUIPMENT TO BE PROVIDED BY ROYAL FREE



Equipment Type	No. Equipment
Base Station – Blood Glucose Monitor	3
Defibrillator AED Biphasic	2
ECG Recorder	1
Flowmeter O2	16
Hoist Electric	1
Pump Suction Portable	2
Regulator Cylinder O2	1
Scale Chair	1
Suction Controller High Suction	16
Thermometer Electronic	16
Beds	16
Trolley Resus	2
Grand Total	77

This is an indicative list and will be updated by the Parties acting reasonably and in good faith taking into consideration HVIVO's particular requirements.

Lab processing, storage and write up space:

Main Lab Equipment	Quantity
1.8M Safety Cabinet	1
1.5M Safety Cabinet	1
Safety Cabinet Stands 1.5M (NB. Potentially to be incorporated into lab fitout costs rather than lab equipment costs TBC by VTF)	1
Safety Cabinet Stands 1.8M (NB. Potentially to be incorporated into lab fitout costs rather than lab equipment costs TBC by VTF)	1
Freezer -80	1
Freezer -20	1
Fridge + 4	1
Refrigerated Centrifuge	2
Ice Machine	1
Microfuge	1

Lab 2 Equipment	Quantity
1.5M Safety Cabinet	1
Safety Cabinet Stands 1.5M (NB. Potentially to be incorporated into lab fitout costs rather than lab equipment costs TBC by VTF)	1
Refrigerated Centrifuge	1
Pipettes	30
Pipette aid	8
Microscopes	2
Vortex	3

Lab within Lab Equipment	Quantity
Freezer -80	1
Fridge + 4	1

Appendix 2

SOFT FM SERVICES

1. OVERVIEW

- 1.1 Royal Free shall provide the following Soft FM Services to the Recipient:
- 1.1.1 cleaning and deep cleaning services;
 - 1.1.2 reception;
 - 1.1.3 waste collection & disposal;
 - 1.1.4 security;
 - 1.1.5 linen and laundry;
 - 1.1.6 portering / post room services;
 - 1.1.7 window cleaning;
 - 1.1.8 pest control; and
 - 1.1.9 entertainment services.
- 1.2 The Soft FM Services shall be provided on a daily basis, Monday to Friday, and at weekends as requested.

2. KEY OBJECTIVES

Royal Free shall:

- 2.1.1 achieve a high level of environmental cleanliness throughout the Premises based upon the methodologies of the National Specifications of Cleanliness in the NHS;
- 2.1.2 provide appropriate collection & disposal of all waste in accordance with the requirements of safe disposal or recycling as set by current legislation;
- 2.1.3 employ a regulated method of patrolling that optimises security and reduces the risk of theft from the organisation, visitors & staff;
- 2.1.4 provide a high quality proactive laundering service; and
- 2.1.5 minimise the risk of pests through a proactive pest control management process

3. SCOPE OF SERVICES AND PERFORMANCE STANDARDS

- 3.1 Royal Free shall comply with all requirements set out in the service level agreement and supporting specifications.
- 3.2 Royal Free shall provide the Soft FM Services on a scheduled, planned and reactive basis as maybe required to meet the agreed level of service.
- 3.3 Royal Free shall be responsible for the cleaning of all functional areas, to the standards and monitoring frequencies (as defined in the National Specification of Cleanliness in the NHS); according to whether they are, in accordance with such Revised Guidance (as such are defined and or updated in the National Specification of Cleanliness in the NHS):

- 3.3.1 Very High Risk Areas;
- 3.3.2 High Risk;
- 3.3.3 Significant Risk Areas; and
- 3.3.4 Low Risk;
- 3.4 Within each of these functional areas Royal Free shall be responsible for cleaning to agreed standards of all elements, except where specifically excluded by the Recipient.
- 3.5 The Recipient shall be responsible for providing a detailed list of clinical and other items not to be included in the cleaning schedule. For the avoidance of doubt Royal Free shall not clean, or move to enable general cleaning, items of equipment so identified by the Recipient unless in agreement with Royal Free's Representative.
- 3.6 Royal Free shall provide a comprehensive waste collection & disposal service and be responsible for the management of all waste produced within the Recipient demise. This shall include the following types of waste:
 - 3.6.1 clinical waste (including 'sharps');
 - 3.6.2 hazardous waste (including but not limited to cytotoxic and cytostatic waste);
 - 3.6.3 domestic waste, including but not limited to:
 - (a) non-recyclable waste; and
 - (b) food waste;
 - 3.6.4 recyclable waste including but not limited to:
 - (a) cardboard and paper;
 - (b) glass; and
 - (c) plastic; and
 - 3.6.5 offensive waste;
- 3.7 Royal Free to identify the standards and procedures for waste management as required by HVIVO. Royal Free to ensure explicit as to following COVID-19 protocols.
- 3.8 Royal Free shall procure the provision of all containers plus the compaction facilities and vehicles to transport Waste from the Premises to appropriate and licensed disposal/recycling sites. The Recipient will provide consumables such as bags and sharps bins.
- 3.9 Portering service provision is based on anticipated patient movements and has been based on the provision of a porter at core times for two days per week. If the portering transfers increase we will need to review the service level. HVIVO will confirm to Royal Free any additional requirements in relation to portering e.g. existing system and timelines for porter transfer or HVIVO having its own dedicated porter and Royal Free will use reasonable endeavours to deliver provided at least 7 days' notice of requirements is provided.
- 3.10 Royal Free shall provide a comprehensive security patrol service as part of its site wide security strategy and in accordance with the NHS SMS national strategy for managing security services in the NHS that shall include the following elements:

- 3.10.1 responding to security incidents;
- 3.10.2 patrols;
- 3.10.3 escort & lone worker duties on request;
- 3.10.4 responding to disaster/emergency contingency plans; and
- 3.10.5 crime prevention advice.
- 3.11 Royal Free shall provide a laundering service that allows for the collection & delivery of items to and from the Trust linen room, as required by the Recipient; chargeable at rate per piece. Linen provided to manage all inpatient beds and the provision of scrub suits for staff.
- 3.12 In the event of a surge in the requirements for scrub suits for staff, Royal Free shall ensure there are plans and procedures in place to ensure demand is met and there are not shortages.
- 3.13 Access to bedside entertainment – smart TV access in each side room with "Freeview HD Package" which offers 24 hour access to a wide variety of channels. Freeview HD is a huge step-up on regular Freeview TV and the perfect match for the HD screens providing free to access digital TV through an existing aerial.
- 3.14 The pest control service shall provide, manage and operate a comprehensive system of pest control management in accordance with the provisions of this specific service specification. Types of pests historically experienced by Trusts in past years have included but are not limited to:
 - 3.14.1 Insects including:
 - (a) Cockroaches;
 - (b) Wasp Nests; and
 - (c) Lice and mites;
 - 3.14.2 Rodents and mammals including:
 - (a) Rattus Norvegicus (common, brown or Norway rat);
 - (b) Rattus Rattus (ship or black rat); and
 - (c) Mus domesticus (house mouse); and
 - 3.14.3 Birds including:
 - (a) Feral pigeons.
- 3.15 Additional pests are not included in the contract as a preventative programme but can be included as and when required chargeable on a per episode basis.

4. SPECIFIC REQUIREMENTS

Ref	Performance Parameters																			
Scheduled Cleaning																				
SP 01	Royal Free shall submit cleaning schedules to the Recipient for approval prior to service commencement and undertake a quarterly review of these schedules to ensure they continue to support agreed activities. Royal Free shall ensure that scheduled cleaning is undertaken within agreed Access Times except where expressly permitted by the Recipient representative in advance.																			
SP 02	Royal Free shall make available a current cleaning schedule to the Recipient within 2 hours of request.																			
SP 03	Royal Free shall ensure that scheduled cleaning in all functional areas has been completed in accordance with the cleaning schedules agreed with the Recipient and the service standards contained within The National Specifications for Cleanliness in the NHS. HVIVO will provide the cleaning schedule to Royal Free.																			
SP 04	Royal Free shall ensure that all cleaning practices comply with the Recipient's control of infection procedures.																			
SP 05	Royal Free shall respond to ad-hoc service requests for cleaning requirements, these will be based upon the following: a) replenishment of Materials/disposables/consumables, e.g. toilet tissue, hand towels, hand cleanser etc.; b) cleans following clinical contamination – additional charge; c) untoward incidents such as flooding – additional charge; d) other reasonable requests in accordance with daily cleaning duties received by the Helpdesk																			
SP 06	All ad-hoc service requests for cleaning duties are attended within 2 hours																			
Planned Cleaning																				
	Planned cleaning tasks are: <table><tr><th>Cleaning Type</th><th>Element/ Area</th><th>Frequency</th></tr><tr><td rowspan="4">Deep Cleans</td><td>Soft Floors</td><td>Annually</td></tr><tr><td>Hard Floors</td><td>Annually</td></tr><tr><td>Soft Furnishings</td><td>Annually</td></tr><tr><td>Kitchens</td><td>Bi annually</td></tr><tr><td rowspan="3">Specialist Cleans</td><td>Laboratories</td><td>Annually</td></tr><tr><td>Aseptic Rooms</td><td>Annually</td></tr><tr><td>UV equipment</td><td>Within 2 hours of notice where required</td></tr></table>	Cleaning Type	Element/ Area	Frequency	Deep Cleans	Soft Floors	Annually	Hard Floors	Annually	Soft Furnishings	Annually	Kitchens	Bi annually	Specialist Cleans	Laboratories	Annually	Aseptic Rooms	Annually	UV equipment	Within 2 hours of notice where required
Cleaning Type	Element/ Area	Frequency																		
Deep Cleans	Soft Floors	Annually																		
	Hard Floors	Annually																		
	Soft Furnishings	Annually																		
	Kitchens	Bi annually																		
Specialist Cleans	Laboratories	Annually																		
	Aseptic Rooms	Annually																		
	UV equipment	Within 2 hours of notice where required																		
SP 07	Royal Free shall agree the requirements for planned cleaning with the Recipient prior to service commencement and undertake a quarterly review of this activity.																			
SP 08	Royal Free shall ensure that planned cleaning activities have been completed & a signature of satisfaction has been obtained from Recipient																			
Materials & cleaning equipment																				
SP 09	Royal Free shall ensure all cleaning equipment used in the delivery of the cleaning service shall be cleaned in accordance with the Recipient's control of infection procedures.																			
SP 10	Royal Free shall ensure that all cleaning equipment used in the delivery of the service is stored to avoid any disruption to the Recipient activities when not in use. Store to be identified by the Recipient staff																			
SP 11	Royal Free shall ensure that cleaning equipment and materials designated for use in specific locations are clearly marked and used only in those locations.																			

Specialist Cleaning	
SP 12	Vapour Hydrogen Peroxide (VHP) specialist cleaning will be deployed once each patient is discharged and prior to the next patient. UV specialist cleaning will be delivered subject to a schedule to be agreed between the parties and subject to the turn around times set out above.

Pest Control	
SP 13	Royal Free shall provide at the commencement of the agreement a schedule of inspection for the forthcoming 6 months, detailing the areas affected and timescales of each item of work. The schedule of monthly inspections shall demonstrate that the Premises is planned to remain free of infestation in accordance with good industry practice and the requirements of legislation at all times. As a minimum two planned preventative site assessments are to be made, one in the winter months and one in the summer months.
SP 14	Royal Free shall provide a reactive pest control service for infestations that occur outside of planned visits and which requires a maximum response of no more than 2 working days.
SP 15	Royal Free shall provide safe, humane and efficient methods of catching, destroying (if appropriate) and safely disposing of pests. The pest control service shall ensure all pest control systems shall be tamper resistant.

Waste General	
SP 16	Royal Free shall instigate systems and procedures for the safe handling, segregation, collection and storage of all waste prior to removal from the Recipient site. Such system(s) shall be based on the providers risk assessment and have the following objectives: <ul style="list-style-type: none"> a) comply with Royal Frees segregation and streaming system; b) minimise handling of waste at all stages; c) implement waste reduction and minimisation measures wherever practicable.
SP 17	The provider shall deliver the waste collection and disposal in accordance with these systems and procedures & the Recipient will comply to the agreed disposal methods.
SP 18	The provider shall provide an appropriate and adequate mix of external storage and transportation containers, and equipment for the removal of waste; consumables to be provided by the Recipient – i.e. bags and sharps bins For the avoidance of doubt waste bag tags are to be provided by the provider

Waste Collections for Disposal

SP 19	Royal Free shall ensure collections of waste are undertaken on Monday, Wednesday & Friday of each week and sharps bins shall be collected on the same basis and as requested.
SP 20	Royal Free shall undertake scheduled waste collections as per SP 19 with no exception

Waste Duty of Care

SP 21	Royal Free shall ensure the Royal Free London NHS Trust is compliant with its duty of care obligations and will maintain <ul style="list-style-type: none"> a) records detailing written description of the sites Waste production which includes: <ul style="list-style-type: none"> i) its nature, source and quality, ii) sufficient information as defined in the NHS General Standards. iii) the audit trail to discharge the Trusts duty of care, iv) any other relevant information likely to affect the handling or disposal of the waste; and b) ensures that the means of treatment and disposal are appropriate to the Waste. c) records the weight, volume and type of all categories of Waste.
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	The nature of the Trust bulk disposal operations means that this level of detail will not be available for the Recipient demise and charges will be based estimated values of number and type of full bulk containers of waste form the central point
Security Incidents	
SP 22	The provider shall ensure that appropriately trained security staff take necessary action and attend incidents where visitors, staff or property are, or are perceived to be at risk of injury or damage.
SP 23	Royal Free shall ensure all on duty security staff are contactable 24/7 via switchboard or a dedicated helpdesk.
SP 24	Royal Free shall provide 1 appropriately qualified and equipped security guard 24/7 to be based / positioned [REDACTED]
Patrols	
SP 25	Royal Free shall develop a programme of frequent but random security patrols of the Recipient demise with a minimum of 3 visits per day. The programme for these shall be based on historical data based on frequency of incidents requiring security response. Patrols shall include patrols of the perimeter and other public areas to provide a high profile deterrent. Particular attention must be paid to all external windows, CO ₂ /Nitrogen store areas, freezer roof and other sensitive or vulnerable areas designated by the Recipient representative.
SP 26	Royal Free shall immediately report any evidence of damage / risk to the Recipient or personal property to the Recipient reception.
SP 27	Royal Free shall investigate all security incidents within an agreed timescale.
SP 28	Royal Free shall secure any doors or windows left open in vacated locations without apparent reason which may present a security risk and switch off lights that are not required.
SP 29	Royal Free shall remove from Premises any loiterers, travellers, hawkers or any other persons who do not have bona fide reason to be on the Premises.
Lone Worker Contact & Escort Duties	
SP 30	Royal Free shall provide a lone worker service ensuring that lone workers are contacted no less than hourly, or as agreed with the member of the Recipient's staff
	Royal Free shall provide routine escort duties whilst the Recipient's staff are undertaking lone worker duties.
Emergency Response	
SP 31	Security staff shall respond to alarms in accordance with pre-arranged procedures, such emergencies may include but are not limited to: a) fire alarms; b) intruder alarms; c) security alarms; d) personal attack alarms.
SP 32	Security staff shall undertake actions as described in fire contingency plans and or as instructed by the fire brigade officers or in accordance with the Recipient fire safety contingency plans.
Grounds	
SP 33	Royal Free shall provide a schedule for grounds cleaning and litter picking & snow gritting service to the immediate area surrounding the Recipient demise.
SP 34	Royal Free shall ensure all fire access ways are kept clear and free from debris at all times.
SP 35	The provider shall ensure that all external staircases / fire escape routes are safe, clearly marked and free from obstruction.

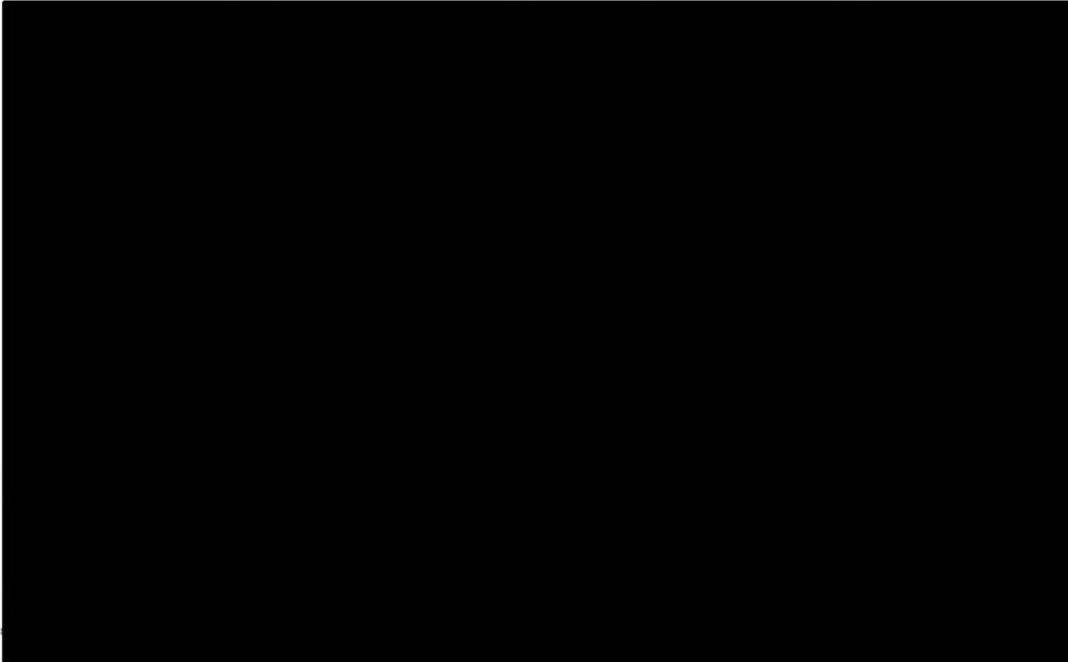
SP 36	Royal Free shall ensure all external pedestrian walkways are free from obstruction.
SP 37	Royal Free shall ensure pathways, roads, car parks, external staircases / fire escapes and other Premises circulation routes remain safe during periods of adverse weather.

<i>Linen Provision</i>	
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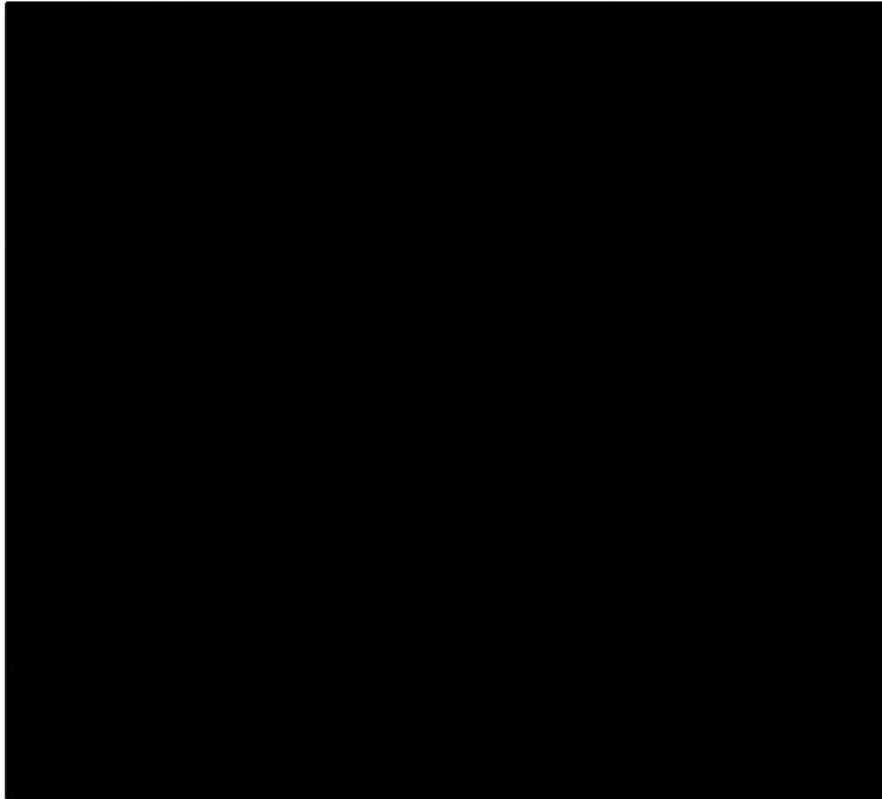
SP 38	The provision of a daily linen service provision for all in-patient bed spaces, staff scrub suit provision and laundering of all linen supplies maintaining a top up service at agreed levels at all times.
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Appendix 3

SERVICE CHARGES



Appendix 4



SCHEDULE 3
PATHOLOGY SERVICES

1. INTERPRETATION

- 1.1 Capitalised terms used in this Schedule are as defined in the relevant SOPs and/or NHS handbooks unless expressed otherwise herein.

2. SCOPE OF SERVICES AND PERFORMANCE STANDARDS

- 2.1 Royal Free will provide the following pathology services at all times in accordance with the operating hours set out at paragraph 5 below and any timeframes set out in the Project Plan and in accordance with this Agreement.

- 2.2 HVIVO will be required to follow the most up to date version of the Royal Free hospital pathology user guide accessible on the Royal Free Intranet Handbook as updated by Royal Free from time to time.

- 2.3 Royal Free shall:

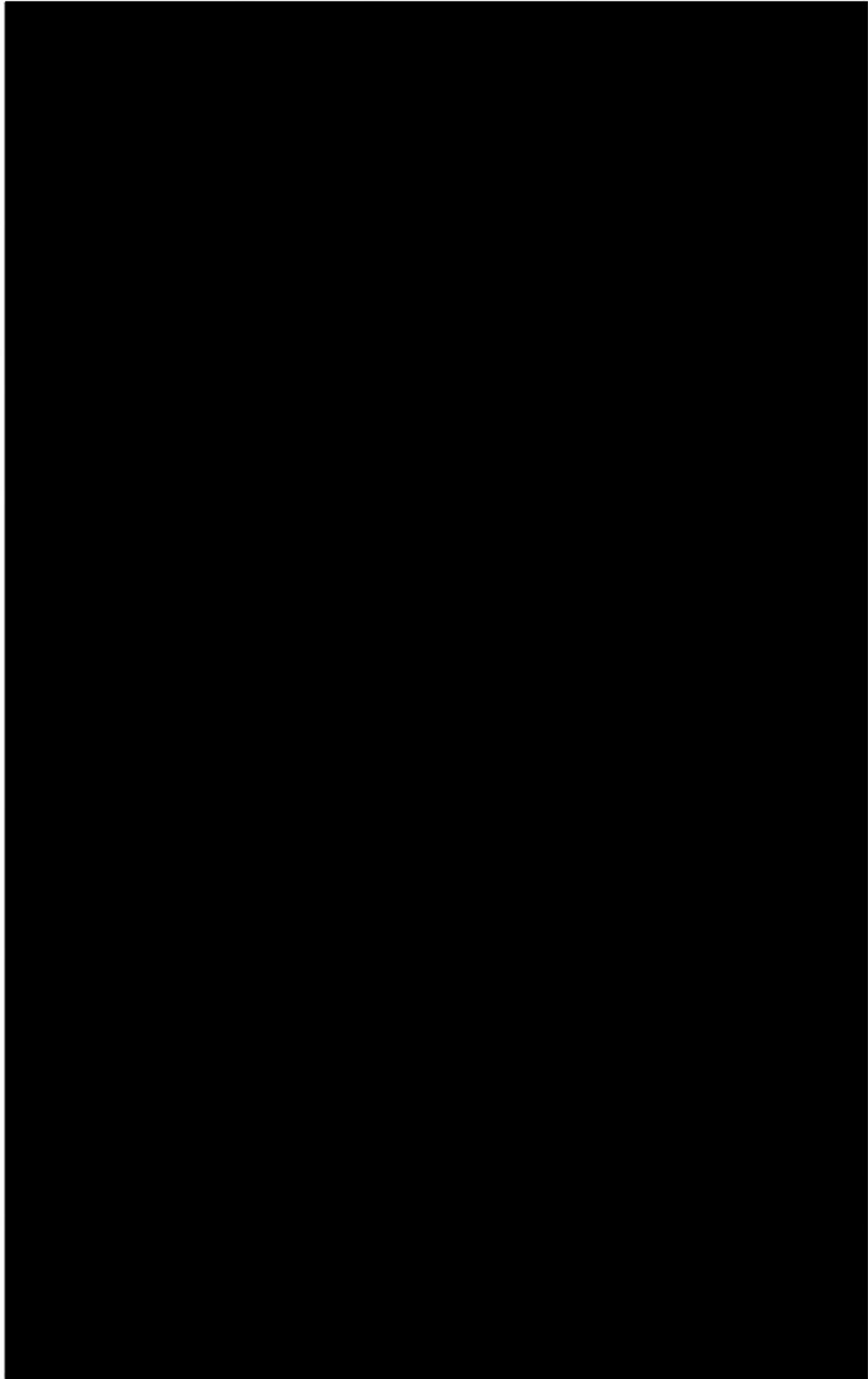
- 2.3.1 Provide the pathology tests in accordance with the lab turn around times ("TAT Targets") set out in Table I (Pathology Tests) below. The timeline for TAT Targets starts running at the point of logging a sample at the lab.

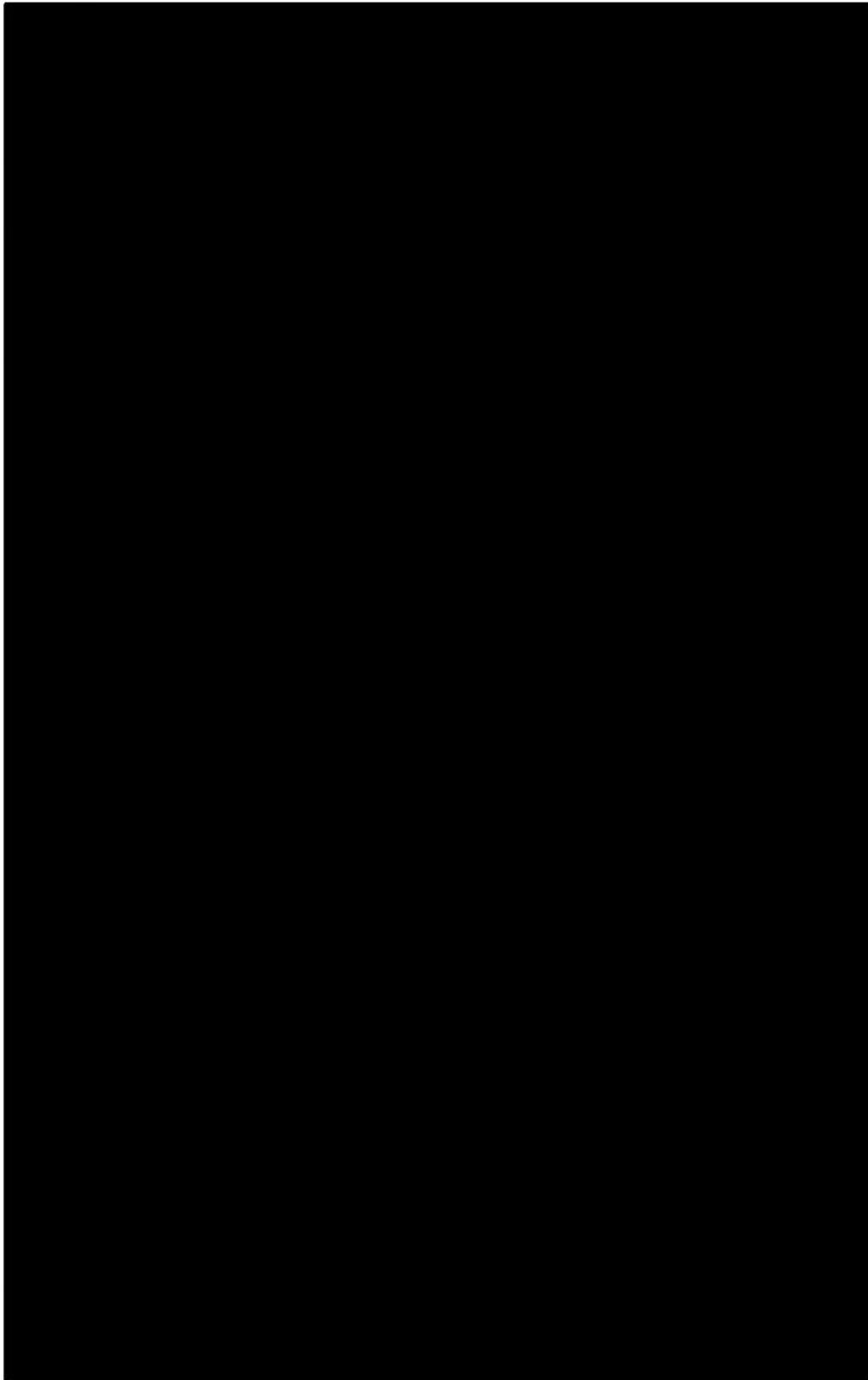
- 2.3.2 Provide urgent tests (in accordance with paragraph 3 below)

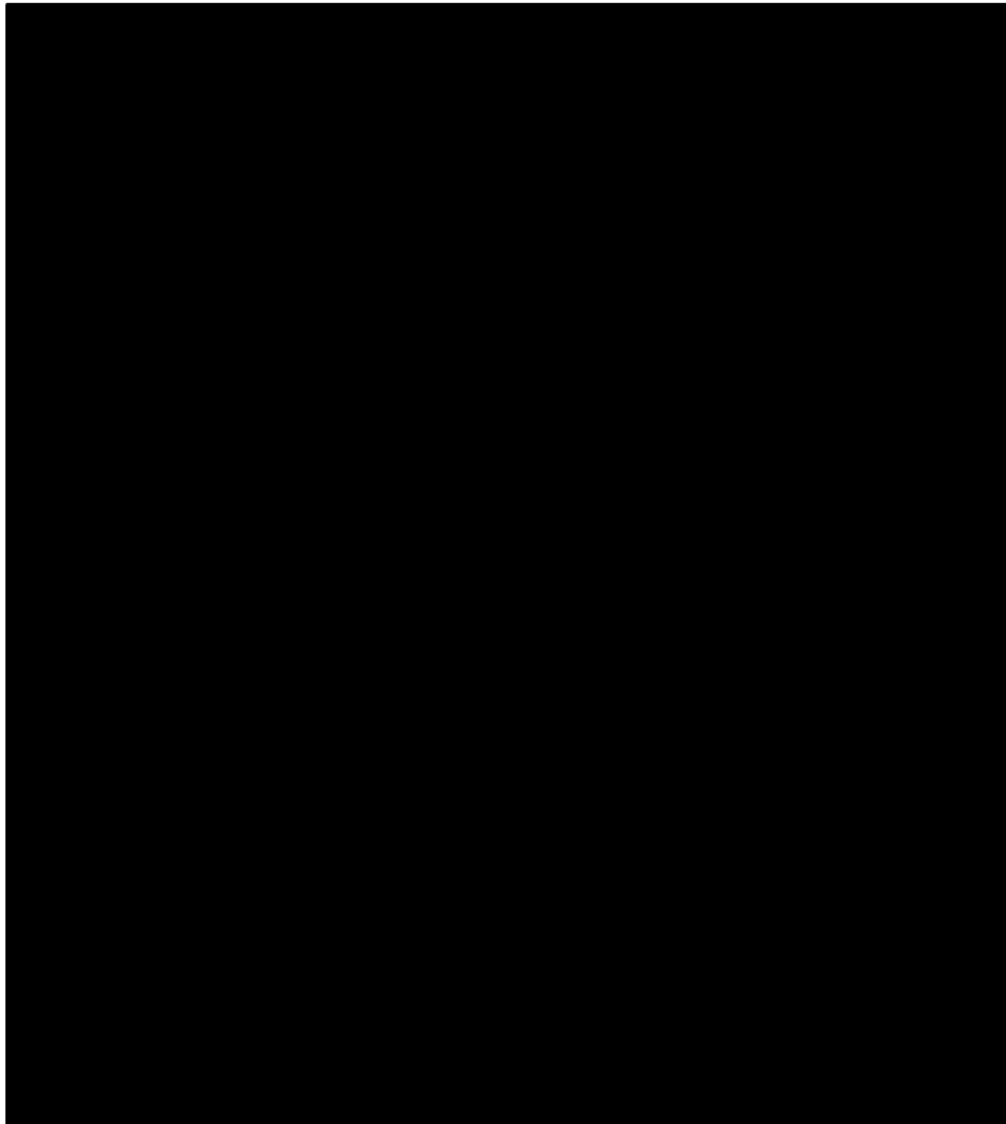
- 2.3.3 Provide sample processing

- 2.3.4 provide shipment and

- 2.3.5 report (in accordance with Table II (Reporting Services) below).







3. **URGENT TEST REQUIREMENTS:**

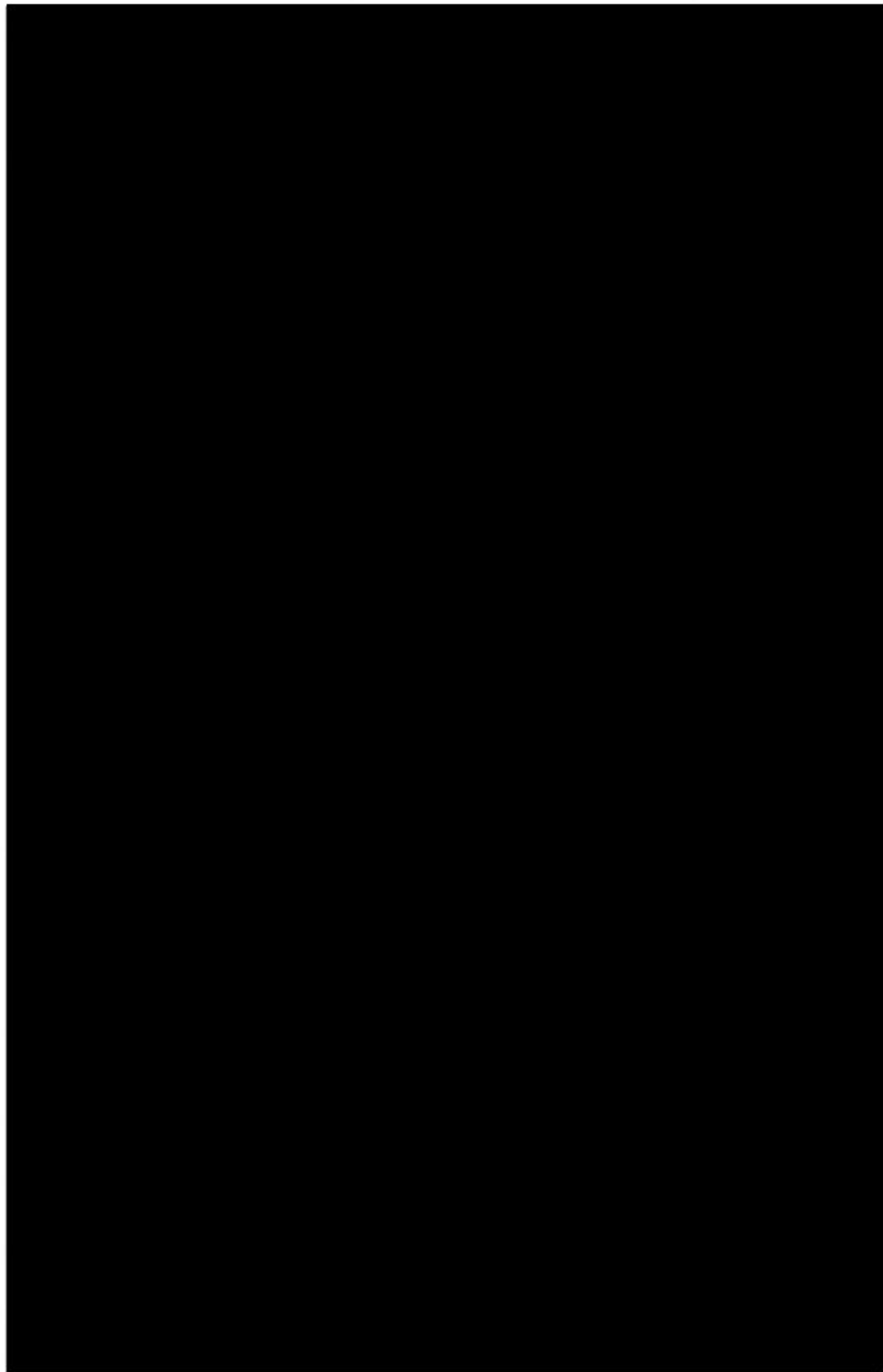
3.1 An urgent request is defined as that which is required for immediate patient management. The definition for an urgent sample is one where the result is likely to affect the management of a patient before the time when a routine sample is likely to be reported. The Rapid Response Laboratory (which is located at the Premises) operates a 24 hour urgent analytical service with the exception of immunology (hours of operation stated below) complementing the routine service including weekends and Bank holidays

3.2 Only clinically urgent samples should be requested urgently.

2.3 **Urgent repertoire:**

Only the following test repertoire is available for our urgent laboratory service

Analytes available on an urgent basis: Biochemistry and Haematology
--



- 3.4 Royal Free will provide urgent tests in accordance with the TAT Target for clinically urgent pathology tests which are stated to have an "Urgent TAT Target" in Table above.

- 3.5 In the event of an emergency where a HVIVO volunteer requires an urgent test, such urgent requests will be treated as any other emergency within the Trust, providing a "Full Blood Count" (FBC) service to Royal Free's A&E department between 08.00 and 20.00 hrs each day.

4. REPORTING

Royal Free will provide the reporting services detailed in Table II (*Reporting Services*) below at all times in accordance with this Agreement. Royal Free will ensure that results are added in a timely manner and will provide access to its usual systems (or a suitable alternative solution) in accordance with the TAT Targets in Table I (*Pathology Tests*).

II. Reporting services	
Deliverable	Timelines
Ensure that the results of pathology Tests produced by the Royal Free's laboratory are authorised after technical validation and clinical validation if appropriate.	
Ensure that the reporting system includes a mechanism for alerting requesting clinicians to the presence of clinically abnormal and unexpected results (single results or within a pattern of results) where there is patient risk and a need for urgent intervention.	
Ensure that individual results or groups of results are combined and issued as a final, consolidated report in electronic form with priority results clearly flagged and that interim pathology reports are marked accordingly.	
Inform and update requestors about their responsibility for taking clinical decisions or action as a consequence of receiving test results, particularly when significantly abnormal results require urgent action, and that the test results are recorded in the patient's health care record.	
Ensure that laboratory reports are available to meet the requirements of the NHS Litigation Authority (NHS LA) Disputes Guidance and to work towards the CNST Level 3 requirements.	
The Pathology Informatics Team will report on service usage and performance and present the same to HVIVO on a monthly basis.	

5. OPERATING HOURS

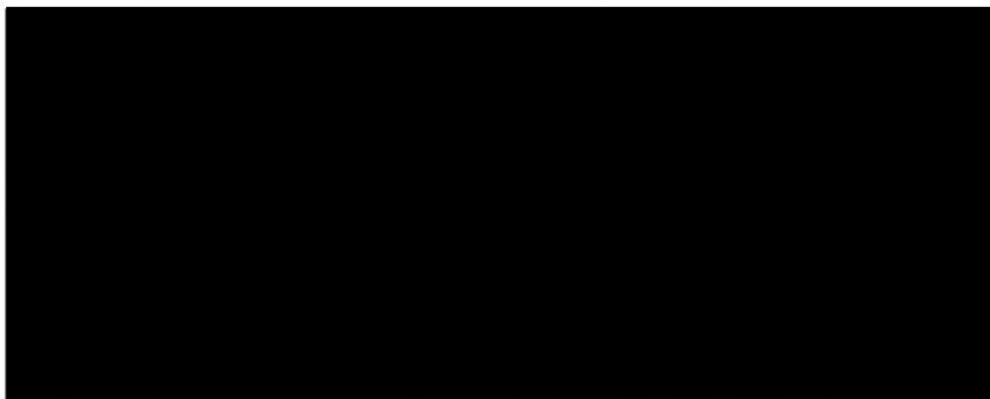
Royal Free shall provide the Pathology Services during operating hours as set out in Table III (*Operating Hours*) below:

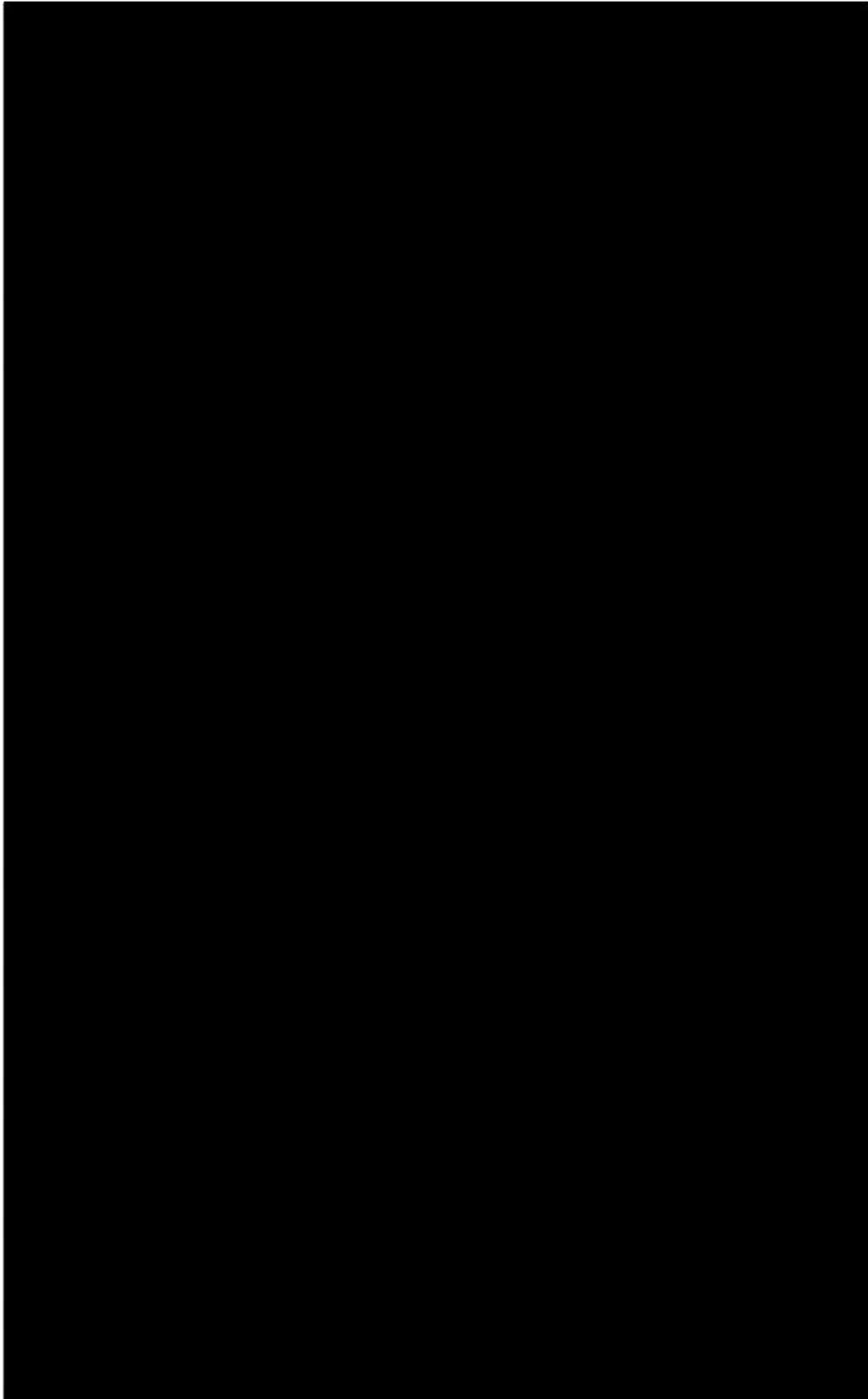
III. Operating Hours		
Department	Routine Hours (Monday – Friday) not including Bank	Out of Hours

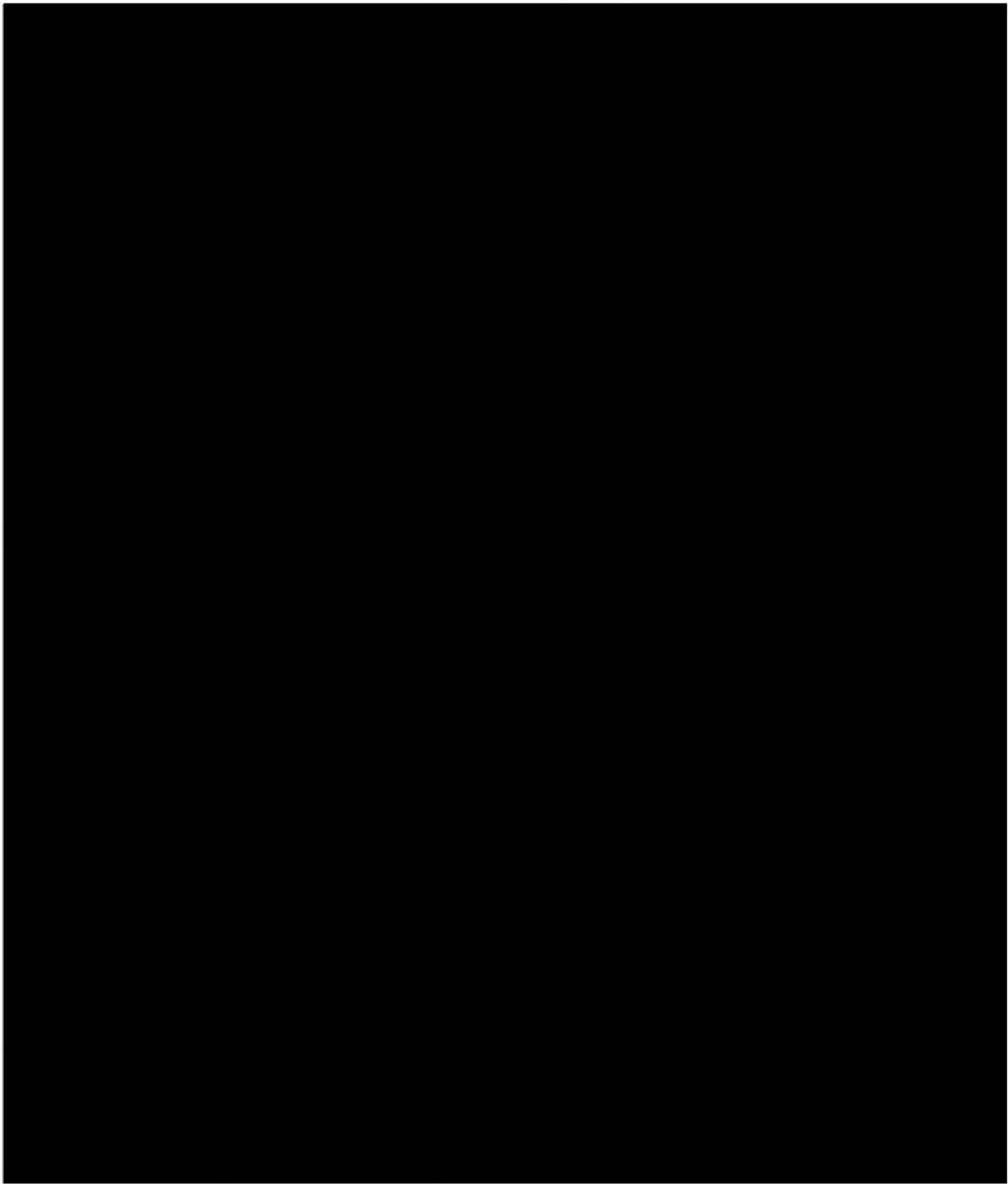
		Holidays	
Blood Transfusion		09.00 – 17.30	A 24 hour shift service is in operation.
Cellular Pathology	Histopath	09.00 – 17.30	17.30 – 09.00 Weekdays 17.30 Friday – 09.00 Monday Bank Holidays.
	Cytopath	09.00 – 17.00	No service provided.
Clinical Biochemistry		09.00 – 17.30	A 24 hour service is provided for urgent requests via the duty officer.
Haematology Departments		09.00 – 17.30	A 24 hour shift service is in operation for the Diagnostic Haematology Department only.
Haemophilia Centre & Thrombosis Unit		09.00 to 17.30 09.00 to 17.00 (Weekends & Bank Holidays)	17.30 – 09.00 Weekdays 17.00 – 09.00 Weekends & Bank Holidays.
Immunology		09.00 to 17.00	No service provided.
Microbiology		08.00 to 08.00	A 24 hour service is provided for urgent requests.
Virology		08.00 to 19.00 09.00 to 16.00 (Sat and Bank Holidays)	Contact on-call Consultant Virologist via RFH switchboard.

6. **SERVICE CHARGES:**

Royal Free will provide the Pathology Services on a cost and volume basis in accordance with the prices set out in Table IV (*Pathology Services Fees*) below (the "**Pathology Services Fees**");







APPENDIX 1

PATHOLOGY HANDBOOK

Last updated November 2019 – Please use most updated file as per Royal Free's hospital internet

SCHEDULE 4
PHARMACY SERVICES

1. INTERPRETATION

- 1.1 Capitalised terms used in this Schedule are as defined in the relevant SOPs and/or NHS handbooks unless expressed otherwise herein.

2. PHARMACY SERVICES

- 2.1 Royal Free shall deliver the Pharmacy Services in accordance with this Schedule 4 and the timings set out in the Project Plan.

- 2.2 Royal Free shall provide the following services:

2.2.1 Set-up and close down

- (a) Review protocol
- (b) Feasibility assessment
- (c) Communication with the sponsor
- (d) Participation in mandatory local review and approval processes
- (e) Attendance at meetings & liaison with PI, Research Nurse, CRA
- (f) Write bespoke SOPs, associated documents and worksheets
- (g) Set up dispensing & stock control software systems and documentation
- (h) Set-up electronic prescribing and pharmacy systems, where applicable
- (i) Set up supply systems
- (j) Train all relevant Pharmacy staff, as required
- (k) Review contract including pharmacy costing
- (l) Close down

2.2.2 Dispensing

- (a) The Authority will procure and Imperial will provide adequate supply of [REDACTED] to Royal Free.
- (b) HVIVO will provide Certificate of Need ("**CON**") medications for what is required on the Premises. Emergency medications and CON are to be agreed with Royal Free as to provision – and to have a replacement process.
- (c) Prescription screening

- (d) Dispensing & labelling
- (e) Routine stock maintenance
- (f) Aseptic compounding incl. essential pre- and post-dose set-up and clean-down
- (g) Dedicated consumables (costed per dose)
- (h) Randomisation of new participants if agreed as a pharmacy role

2.2.3 IMP Management Activities

- (a) Temperature management activities other than providing evidence of temperature to sponsors
- (b) Temperature excursion management
- (c) Expiry date checking
- (d) Specialist clinical trial pharmacy staff
- (e) Full engagement in the trial from initiation visit and set up through to trial closure.
- (f) Generation of all supplementary trial documentation required
- (g) Storage of the IMP in line with MHRA requirements with continual monitoring.
- (h) Full IMP accountability
- (i) Completion of all trial documentation required in line with sponsor requirements
- (j) IMP return processing
- (k) HVIVO will provide all concomitant medications.

2.3 The following services are excluded from the Pharmacy Services:

- 2.3.1 out of hours cover, with the exception of emergency requirements;
- 2.3.2 clinical pharmacy service to the trial participants whilst on the ward;
- 2.3.3 any trial participant medication supplies required outside of the trial;
- 2.3.4 discharge medication supplies.

3. SCOPE OF SERVICES AND PERFORMANCE STANDARDS

- 3.1 Royal Free will provide the pharmacy services detailed in paragraph 2.2 above at all times in accordance with this Agreement and with GMP (the "**Pharmacy Services**"). The services of a GMP pharmacy are required to store, dispense and manage the remdesivir rescue medication for the Study. No other medication services are required for the Study.

4. **SERVICE CHARGES**

- 4.1 The Service Charges payable in respect of the Pharmacy Services are included within the Hard and Soft FM Service Charges.

SCHEDULE 5
RADIOLOGY SERVICES

1. INTERPRETATION

- 1.1 Capitalised terms used in this Schedule are as defined in the relevant SOPs and/or NHS handbooks unless expressed otherwise herein.

2. SCOPE OF SERVICES

- 2.1 Royal Free will provide the following radiology services detailed in Table I (*Radiology Services*) below at all times in accordance with:

2.1.1 the Radiology Service levels; and

2.1.2 the Agreement,

(the "**Radiology Services**").

I. Radiology Services	
Service	Service Level/ Timeline (as appropriate)
<u>Tests and scans</u>	
Royal Free shall provide capacity for CT Scanning and X-Ray.	[REDACTED]
<u>Request and Booking – Diagnostic tests</u>	
Royal Free will provide a non-medical referrer system which enables HVIVO to have access to the systems necessary to raise requests	Timeline of the Study
<u>Where Royal Free request diagnostic test</u> Royal Free will provide a medical employee as the clinician in charge of care, who will request diagnostic tests utilising the electronic order communications system at Royal Free Hospital. The medical employee provided by Royal Free will be registered to request under the Trust medical exposures handbooks in line with IR(ME)R 2000. The request must be placed onto the system and the Royal Free Radiology Department notified 24 hours in advance of the diagnostic to ensure appropriate arrangements can be made to safely	Co-ordination of the patient for the test will be commensurate with standard diagnostics procedures.

perform the test.	
Any issues must be raised through the Radiology Department Operational Manager.	
<u>Where HVIVO request diagnostic test</u> The request must be placed onto the system and the Royal Free Radiology Department notified 24 hours in advance of the diagnostic to ensure appropriate arrangements can be made to safely perform the test.	Where HVIVO make the request HVIVO will ensure to notify the Royal Free Radiology Department 24 hours in advance of the diagnostic.
<u>Request and Booking – Radiology tests and procedures</u>	
Ordering of all radiology tests and procedures.	Performed by authorised clinical staff in accordance with Trust procedures.
Imaging procedures	Vetted by a IR(ME)R practitioner in line with Royal Free IR(ME)R procedures and the request must be clinically justified and requested by an authorised IR(ME)R requestor.
<u>Recovery and portering</u>	
The Royal Free Radiology Department will following a valid request place the request onto the portering system so patients can be brought to the Royal Free Radiology Department. Appropriate PPE will need be worn and notification of the infectious status of the patient is required.	
HVIVO will provide the portering services for the patients and will escort the volunteers to and from the radiology unit OR Patients will be transferred between the ward and department by the porter services within the Trust and in keeping with clinical priority. The transfer procedures will be dependent upon and in line with IPC procedures in place.	The transfer procedures will be dependent upon and in line with IPC procedures in place.
Recovery will not be required for these patients however a clinically ill patient may require a nurse escort which must be arranged by the clinical team in keeping with standard procedures.	Only for clinically ill patients and where arranged in keeping with standard procedures.
<u>Special Requirements and Emergencies</u>	
Royal Free will provide a non-medical referrer system which enables HVIVO to have access to the systems necessary to raise urgent and emergency requests.	Timeline of the Study
HVIVO staff will ensure that an interpreter is provided should there be a patient need.	As this arises according to patient need.

In the event of an emergency where a HVIVO volunteer requires an emergency slot in one of the modalities, the manager appointed by HVIVO for the Services (the " HVIVO Service Delivery Manager ") will speak directly with the Patient Pathway Co-ordinator and / or the Radiology Operations Manager to organise an emergency slot in accordance with standard procedures.	Emergency requests will be treated as any other emergency within the Trust.
If the patient deteriorates and a clinical urgent scan is required the patient will be brought to the Royal Free Radiology Department within scheduled timescales ensuring close liaison to manage patients in line with IPC procedures.	Standard emergency/urgent turnaround times in agreement with the clinical teams
Cancellations	
In the event that HVIVO need to cancel a Radiology booking, the Patient Pathway Co-ordinator will be informed as soon as possible to ensure that this slot can be given to another booking, or can be given to the Royal Free Radiology Department to be filled.	As soon as possible and in any event with no less than 24hours notice from HVIVO. Any slots cancelled with less than 24 hours notice will be charged as scan bookings to account for loss in time.
Reports	
The Informatics Team will report on service usage and performance and present the same to HVIVO.	Monthly.
Royal Free Radiology Department will provide a clinical report on the scan.	Within 24 hours of acquisition of the scan.

3. SERVICE CHARGES

- 3.1 Royal Free will provide the Radiology Services in accordance with the prices set out in Table II (*Radiology Service Fees*) below (the "**Radiology Services Fees**");

II. Radiology Service Fees	
Test	Test Price in GBP £ Sterling (Exc VAT)

SCHEDULE 6

DATA PROTECTION

1. INTERPRETATION

- 1.1 Capitalised terms used in this Schedule are as defined in the relevant SOPs and/or NHS handbooks unless expressed otherwise herein.

2. DEFINITIONS

- 2.1 In this Schedule 6 the following definitions shall apply:

"Data Protection Laws" means (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the Processing of Personal Data to which a Party is subject, including the Data Protection Act 1998 ("**DPA**") and EC Directive 95/46/EC (the "**DP Directive**") (up to and including 24 May 2018) and on and from 25 May 2018, the GDPR and all legislation enacted in the UK in respect of the protection of personal data; and (b) any code of practice or guidance published by the ICO (or equivalent regulatory body) from time to time;

"Data Subject", "Controller", "Data Subject Request", "Data Processing", "Data Protection Officer", "Personal Data", "Personal Data Breach", "Processor" and "Sub-processor" shall have the meanings set out in the Data Protection Laws and "**Process**" and "**Processed**" when used in relation to the processing of personal data, shall be construed accordingly. Any reference to "**Personal Data**" includes a reference to "**Special Categories of Personal Data**" and "**Personal Data relating to Criminal Convictions and Offences**", as applicable, whereby such terms mean personal data that incorporates such categories of data as are listed in Article 9(1) of the GDPR and Article 10 of the GDPR respectively;

"Information Commissioner or ICO" means the UK Information Commissioner's Office, or any successor or replacement body from time to time; and

"Processor Personnel" means all directors, officers, employees, agents, consultants and suppliers of the Processor and/or of any Sub-Processor engaged in the performance of its obligations under this Agreement;

3. PROTECTION OF PERSONAL DATA

Status of the Controller

- 3.1 The Parties acknowledge that for the purposes of the Data Protection Legislation, the nature of the activity carried out by each of them in relation to their respective obligations under this Agreement will determine the status of each Party under the Data Protection Legislation. A Party may act as:

- 3.1.1 "**Controller**" (where the other Party acts as the "Processor");

- 3.1.2 **"Processor"** (where the other Party acts as the "Controller");
- 3.1.3 **"Joint Controller"** (where both Parties are considered to jointly control the same Personal Data);
- 3.1.4 **"Independent Controller"** of the Personal Data where the other Party is also "Controller" of the same Personal Data in its own right (but there is no element of Joint Control (as defined in Clause 3.1.3);

and the Parties shall set out in this Schedule 6 which scenario or scenarios are intended to apply under this Agreement.

Where one Party is Controller and the other Party its Processor

- 3.2 Where a Party is a Processor, the only Processing that it is authorised to do is listed in Schedule 6 by the Controller.
- 3.3 The Processor shall notify the Controller immediately if it considers that any of the Controller's instructions infringe the Data Protection Legislation.
- 3.4 The Processor shall provide all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment prior to commencing any Processing. Such assistance may, at the discretion of the Controller, include:
 - 3.4.1 a systematic description of the envisaged Processing operations and the purpose of the Processing;
 - 3.4.2 an assessment of the necessity and proportionality of the Processing operations in relation to the Services;
 - 3.4.3 an assessment of the risks to the rights and freedoms of Data Subjects; and
 - 3.4.4 the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.
- 3.5 The Processor shall, in relation to any Personal Data Processed in connection with its obligations under this Agreement:
 - 3.5.1 process that Personal Data only in accordance with Schedule 6, unless the Processor is required to do otherwise by Law. If it is so required the Processor shall promptly notify the Controller before Processing the Personal Data unless prohibited by Law;
 - 3.5.2 ensure that it has in place Protective Measures, which the Controller may reasonably reject (but failure to reject shall not amount to approval by the Controller of the adequacy of the Protective Measures) having taken account of the:
 - (a) nature of the data to be protected;
 - (b) harm that might result from a Data Loss Event;
 - (c) state of technological development; and
 - (d) cost of implementing any measures;
 - 3.5.3 ensure that:

- (a) the Processor Personnel do not process Personal Data except in accordance with this Agreement (and in particular Schedule 6);
 - (b) it takes all reasonable steps to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that they:
 - (i) are aware of and comply with the Processor's duties under this Clause 3.5.3 and Clause 11;
 - (ii) are subject to appropriate confidentiality undertakings with the Processor or any Sub-processor;
 - (iii) are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third Party unless directed in writing to do so by the Controller or as otherwise permitted by this Agreement; and
 - (iv) have undergone adequate training in the use, care, protection and handling of Personal Data;
- 3.5.4 not transfer Personal Data outside of the EU unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:
 - (a) the Controller or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with GDPR Article 46 or DPA 2018 Section 75) as determined by the Controller;
 - (b) the Data Subject has enforceable rights and effective legal remedies;
 - (c) the Processor complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Controller in meeting its obligations); and
 - (d) the Processor complies with any reasonable instructions notified to it in advance by the Controller with respect to the Processing of the Personal Data; and
- 3.5.5 at the written direction of the Controller, delete or return Personal Data (and any copies of it) to the Controller on termination of the Agreement unless the Processor is required by Law to retain the Personal Data.
- 3.6 Subject to Clause 3.7, the Processor shall notify the Controller immediately if it:
 - 3.6.1 receives a Data Subject Request (or purported Data Subject Request);
 - 3.6.2 receives a request to rectify, block or erase any Personal Data;
 - 3.6.3 receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;
 - 3.6.4 receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data Processed under this Agreement;
 - 3.6.5 receives a request from any third Party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or

- 3.6.6 becomes aware of a Data Loss Event.
- 3.7 The Processor's obligation to notify under Clause 3.6 shall include the provision of further information to the Controller in phases, as details become available.
- 3.8 Taking into account the nature of the Processing, the Processor shall provide the Controller with reasonable assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under Clause 3.6 (and insofar as possible within the timescales reasonably required by the Controller) including by promptly providing:
- 3.8.1 the Controller with full details and copies of the complaint, communication or request;
 - 3.8.2 such assistance as is reasonably requested by the Controller to enable it to comply with a Data Subject Request within the relevant timescales set out in the Data Protection Legislation;
 - 3.8.3 the Controller, at its request, with any Personal Data it holds in relation to a Data Subject;
 - 3.8.4 assistance as requested by the Controller following any Data Loss Event; and/or
 - 3.8.5 assistance as requested by the Controller with respect to any request from the Information Commissioner's Office, or any consultation by the Controller with the Information Commissioner's Office.
- 3.9 The Processor shall maintain complete and accurate records and information to demonstrate its compliance with this Clause. This requirement does not apply where the Processor employs fewer than 250 staff, unless:
- 3.9.1 the Controller determines that the Processing is not occasional;
 - 3.9.2 the Controller determines the Processing includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR; or
 - 3.9.3 the Controller determines that the Processing is likely to result in a risk to the rights and freedoms of Data Subjects.
- 3.10 The Processor shall allow for audits of its Data Processing activity by the Controller or the Controller's designated auditor.
- 3.11 The Parties shall designate a Data Protection Officer if required by the Data Protection Legislation.
- 3.12 Before allowing any Sub-processor to process any Personal Data related to this Agreement, the Processor must:
- 3.12.1 notify the Controller in writing of the intended Sub-processor and Processing;
 - 3.12.2 obtain the written consent of the Controller;
 - 3.12.3 enter into a written agreement with the Sub-processor which give effect to the terms set out in this Schedule 6 such that they apply to the Sub-processor; and
 - 3.12.4 provide the Controller with such information regarding the Sub-processor as the Controller may reasonably require.

- 3.13 The Processor shall remain fully liable for all acts or omissions of any of its Sub-processors.
- 3.14 The Authority may, at any time on not less than 30 Business Days' notice, revise this Clause by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Agreement).
- 3.15 The Parties agree to take account of any guidance issued by the Information Commissioner's Office. The Authority may on not less than 30 Business Days' notice to Royal Free amend this Agreement to ensure that it complies with any guidance issued by the Information Commissioner's Office.

Where the Parties are Joint Controllers of Personal Data

- 3.16 In the event that the Parties are Joint Controllers in respect of Personal Data under this Agreement, the Parties shall implement Clauses that are necessary to comply with GDPR Article 26 based on the terms set out in Schedule 6.

Where the Parties are Independent Controllers of Personal Data

- 3.17 With respect to Personal Data provided by one Party to another Party for which each Party acts as Controller but which is not under the Joint Control of the Parties, each Party undertakes to comply with the applicable Data Protection Legislation in respect of their Processing of such Personal Data as Controller.
- 3.18 Each Party shall process the Personal Data in compliance with its obligations under the Data Protection Legislation and not do anything to cause the other Party to be in breach of it.
- 3.19 Where a Party has provided Personal Data to the other Party in accordance with Clause 3.17, the Recipient of the Personal Data will provide all such relevant documents and information relating to its data protection policies and procedures as the other Party may reasonably require.
- 3.20 The Parties shall be responsible for their own compliance with Articles 13 and 14 GDPR in respect of the Processing of Personal Data for the purposes of this Agreement.
- 3.21 The Parties shall only provide Personal Data to each other:
- 3.21.1 to the extent necessary to perform the respective obligations under this Agreement;
 - 3.21.2 in compliance with the Data Protection Legislation (including by ensuring all required fair Processing information has been given to affected Data Subjects); and
 - 3.21.3 where it has recorded it in Schedule 6.
- 3.22 Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of Processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, each Party shall, with respect to its Processing of Personal Data as Independent Controller, implement and maintain appropriate technical and organisational measures to ensure a level of security appropriate to that risk, including, as appropriate, the measures referred to in Article 32(1)(a), (b), (c) and (d) of the GDPR, and the measures shall, at a minimum, comply with the requirements of the Data Protection Legislation, including Article 32 of the GDPR.

- 3.23 A Party Processing Personal Data for the purposes of this Agreement shall maintain a record of its Processing activities in accordance with Article 30 GDPR and shall make the record available to the other Party upon reasonable request.
- 3.24 Where a Party receives a request by any Data Subject to exercise any of their rights under the Data Protection Legislation in relation to the Personal Data provided to it by the other Party pursuant to this Agreement ("**the Request Recipient**"):
- 3.24.1 the other Party shall provide any information and/or assistance as reasonably requested by the Request Recipient to help it respond to the request or correspondence, at the cost of the Request Recipient; or
- 3.24.2 where the request or correspondence is directed to the other party and/or relates to the other party's Processing of the Personal Data, the Request Recipient will:
- (a) promptly, and in any event within five (5) Business Days of receipt of the request or correspondence, inform the other party that it has received the same and shall forward such request or correspondence to the other party; and
- (b) provide any information and/or assistance as reasonably requested by the other party to help it respond to the request or correspondence in the timeframes specified by Data Protection Legislation.
- 3.25 Each party shall promptly notify the other Party upon it becoming aware of any Personal Data Breach relating to Personal Data provided by the other party pursuant to this Agreement and shall:
- 3.25.1 do all such things as reasonably necessary to assist the other Party in mitigating the effects of the Personal Data Breach;
- 3.25.2 implement any measures necessary to restore the security of any compromised Personal Data;
- 3.25.3 work with the other Party to make any required notifications to the Information Commissioner's Office and affected Data Subjects in accordance with the Data Protection Legislation (including the timeframes set out therein); and
- 3.25.4 not do anything which may damage the reputation of the other Party or that Party's relationship with the relevant Data Subjects, save as required by Law.
- 3.26 Personal Data provided by one Party to the other Party may be used exclusively to exercise rights and obligations under this Agreement as specified in Schedule 6.
- 3.27 Personal Data shall not be retained or Processed for longer than is necessary to perform each Party's obligations under this Agreement which is specified in Schedule 6.
- 3.28 Notwithstanding the general application of Clauses 3.2 to 3.15 to Personal Data, where Royal Free is required to exercise its regulatory and/or legal obligations in respect of Personal Data, it shall act as an Independent Controller of Personal Data in accordance with Clause 3.16 to 3.27.

DATA PROCESSING PARTICULARS

1. Subject-matter of the Processing

- 1.1 Processing is necessary for the provision of Services to the Characterisation Study.
- 2. Duration of the Processing**
 - 2.1 Processing will continue for the full term of the Agreement.
- 3. Nature and Purpose of Processing**
 - 3.1 Personal Data shall be Processed and in particular shall be collected, retrieved, stored, used etc for the purpose of provision of Services to the Characterisation Study
 - 3.2 This will include Processing for the purpose of:
 - 3.2.1 providing test and scan results to the Recipient
 - 3.2.2 providing meals to the volunteers
- 4. Types of Personal Data**
 - 4.1 The types of Personal Data that shall be Processed in accordance with this Agreement will be:
 - 4.1.1 Information may include names, telephone numbers, email address, postal address, Hospital number and date of birth.
 - 4.2 The types of Special Categories of Personal Data that shall be Processed in accordance with this Agreement will be:
 - 4.2.1 personal data revealing: racial or ethnic origin and data concerning health or sexual orientation.
- 5. Categories of Data Subjects**
 - 5.1 The categories of individuals whose Personal Data is Processed in accordance with this Agreement will be:
 - 5.1.1 volunteers for the Characterisation Study.
 - 5.1.2 details of HVIVO staff members.
- 6. Processing Instructions**
 - 6.1 Data to be Processed in accordance with GDPR regulations or any subsequent Data Protection Legislation.

SCHEDULE 7

CAPITAL INVESTMENT

1. INTERPRETATION

- 1.1 Capitalised terms used in this Schedule are as defined in the relevant SOPs and/or NHS handbooks unless expressed otherwise herein.

2. BACKGROUND AND PURPOSE

- 2.1 The Authority, Royal Free and HVIVO have been working together to identify the location, specifications and equipment required to develop a human challenge model and deliver the Project.

2.2

[REDACTED]

- 2.3 As part of the Study, lab facilities are required in the hospital so that samples can be processed, stored and shipped to HVIVO's laboratories in Whitechapel for analysis. The laboratories identified are located on the ground floor. These labs have been out of service for a number of years and refurbishment (including ventilation and a new specimen chute works) and new equipment is required, in line with HVIVO's required specifications.

- 2.4 Not directly linked to the trial, but as a direct consequence of offering up the trust's [REDACTED]
[REDACTED] In the limited time available it is essential that the trust undertake the necessary fire and medical gas compliance works in order for the ward to be able to function from 1st December 2020.

3. AGREED CAPITAL INVESTMENT

- 3.1 In consideration of the above, the Authority will pay to Royal Free:

- 3.2 [REDACTED] respect of the HVIVO Lab refurbishment; and

- 3.3 [REDACTED] ward refurbishment,

(together the "Capital Investment").

4. PAYMENT SCHEDULE

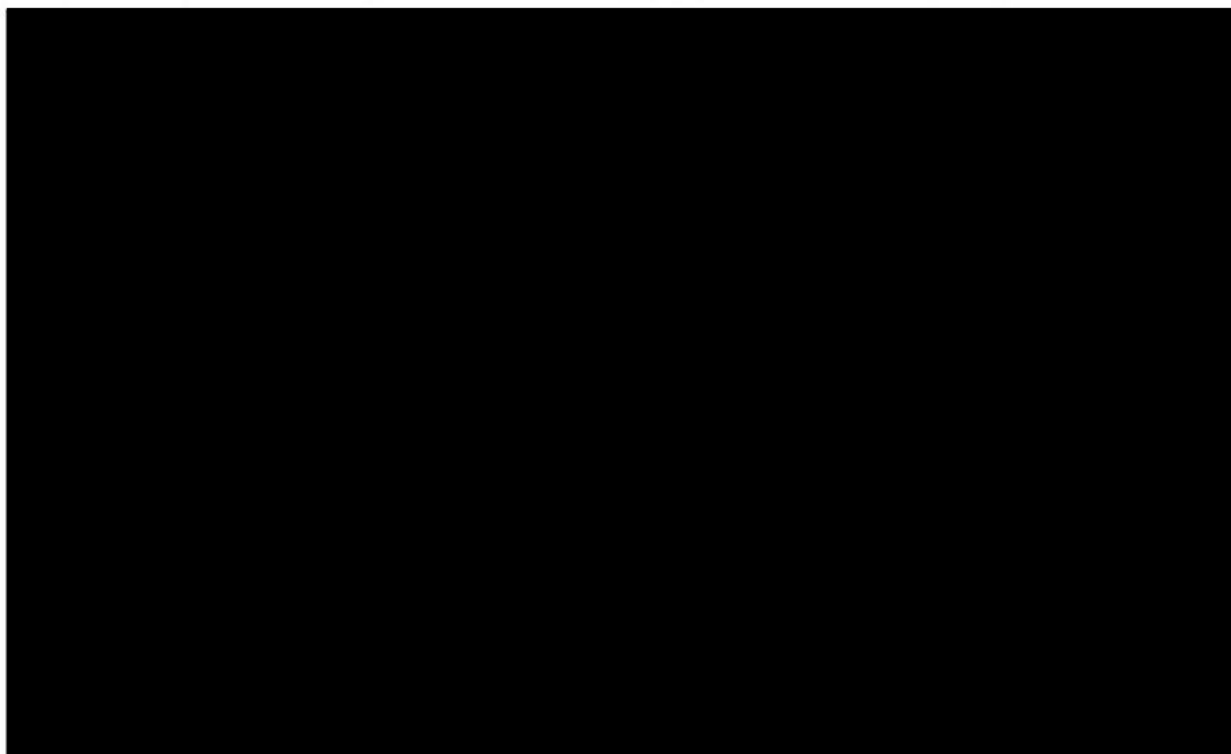
- 4.1 The Authority will pay the Capital Investment in accordance with the following milestone payment schedule with a payment term of 30 days from receipt of the relevant invoice:

- 4.1.1 35% on the Commencement Date;

- 4.1.2 35% on the handover of [REDACTED] (indicatively 2nd December); and

- 4.1.3 30% on the handover of labs (indicatively 16th December).

APPENDIX 1



SCHEDULE 8
CARDIOLOGY SERVICES

1. INTERPRETATION

- 1.1 Capitalised terms used in this Schedule are as defined in the relevant SOPs and/or NHS handbooks unless expressed otherwise herein.

2. SCOPE OF SERVICES AND PERFORMANCE STANDARDS

2.1 Scanning

- 2.1.1 The Cardiology Department will provide capacity for scanning and reporting on a schedule to be agreed in advance with HVIVO across, [REDACTED] the number of which is detailed in section 3 below.

- 2.1.2 This level of capacity is designed to meet service levels as described within section 2 below.

2.2 Request and booking procedures

- 2.2.1 The Transthoracic echocardiogram test will be requested via email by HVIVO staff (an email address will be provided). Diagnostic requests must be sent in advance for the planned date required and clearly specified.

- 2.2.2 Co-ordination of the patient for the test will be commensurate with standard diagnostics procedures. Any issues must be raised through the cardiology department senior operational manager.

3. DIAGNOSTIC SERVICE LEVELS

- 3.1 The Cardiology Department will ensure timely access of patients in line with agreed protocol as per the following arrangements:

3.1.1 Standard capacity commitments

- (a) The Cardiology department will deliver the service commensurate with the planned timescales in line with the trial. The request must be placed onto the system and Cardiology notified 48 hours in advance of the diagnostic to ensure appropriate arrangements can be made to safely perform the test.
- (b) If the patient deteriorates and a clinical urgent scan is required this will fall under the standard emergency/urgent turnaround times and in agreement with the clinical teams. Cardiology will not be responsible where a patient is clinically unable undergo the tests within the scheduled timescales and ensuring close liaison to manage patients in line with IPC procedures is required.

4. OPERATIONAL PROCEDURES

4.1 Booking of Cardiology slots

- 4.1.1 Ordering of all cardiology tests and procedures will be performed by authorised clinical staff in accordance with Trust procedures.

- 4.1.2 The request must be made to the Cardiology team using a monitored email address (an email address will be provided) at least 48 hours before the test is required.

4.2 Special requirements

- 4.2.1 HVIVO staff will ensure that an interpreter is provided should there be a patient need for patient consent.

4.3 Emergencies

- 4.3.1 In the event of an emergency with a HVIVO volunteer requiring an emergency slot, the HVIVO Service Delivery Manager will speak directly with the patient pathway co-ordinator and / or the Cardiology Senior Operations Manager to organise an emergency slot.
- 4.3.2 Emergency requests will be treated as any other emergency within the Trust.

4.4 Patient scan

- 4.4.1 The cardiology department will following a valid request, arrange for the scan to be undertaken on the ward in using the dedicated equipment stored on the ward. Appropriate PPE will need to be worn and notification of the infectious status of the patient is required. For infection control reasons the cardiology staff will not be able to return to the department following the procedure and scans will be scheduled to accommodate this (e.g in the afternoon). Scheduling for multiple volunteers will be agreed in advance with cardiology team.

4.5 Cancellations

- 4.5.1 In the event that HVIVO need to cancel a cardiology booking, the Patient Pathway Co-ordinator will be informed as soon as possible to ensure that this slot can be given to another booking if applicable.
- 4.5.2 Any slots cancelled with less than 24 hours notice will be charged as scan bookings for loss in time.

5. SERVICE QUALITY

5.1 Reporting of results

- 5.1.1 Cardiology will provide a clinical report on the scan directly following the test or next day if the test is late in the afternoon.
- 5.1.2 Any diagnostic test outside of the defined contractual agreement in response to the deteriorating patient will fall under standard NHS care

6. SERVICE CHARGES

