

AMENDMENT AND RESTATEMENT OF MASTER SERVICES RENDERED AGREEMENT

BETWEEN

THE UNIVERSITY

AND

HOSPITALS NHS TRUST

CONTENTS

CLAUSE

1.	Definitions and Interpretation	1
2.	Master Agreement and Works Request	3
3.	Obligations of the Parties	3
4.	Finance	3
5.	Results	4
6.	Confidential Information	4
7.	Data Protection and Freedom of Information	5
8.	Governance and Compliance	6
9.	Project Materials	7
10.	Warranty and Liability	7
11.	Term and Termination	7
12.	Entire Agreement and Variation	8
13.	No Waiver	8
14.	Assignment	8
15.	Notices	8
16.	No Partnership	9
17.	Third Party Rights	9
18.	Counterparts	9
19.	Governing Law and Jurisdiction	9

SCHEDULE

APPENDIX 1: WORKS REQUEST	11
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Amendment and Restatement of Master Services Rendered Agreement (the "Agreement")

This Master Services Rendered Agreement (the "**Prior Agreement**"), is hereby amended and restated herein. This Agreement is made between:

PARTIES

- (1) **The University of Xxxxx** a body incorporated in England and Wales by Royal Charter with registration number whose principal offices are at *Insert Address*
- (2) **Xxxxx University Hospitals NHS Trust** of *Insert Address*

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

BACKGROUND

The Parties entered into the Prior Agreement on 9 December 2019. Following discussions between the Parties, it has been agreed to amend the Prior Agreement in its entirety as restated herein.

THE HOSPITAL wishes to utilise the medical imaging equipment and services of The University's (**THE UNIVERSITY IMAGING CENTRE**) between 9th March 2026 and 31st December 2031 for the purpose of carrying out ethically approved clinical research projects. The University has agreed to allow access to its MRI scanning facilities in accordance with the terms and conditions set out below.

The Parties therefore wish to establish this Master Services Rendered Agreement (**Master Agreement**), **effective as of xxxxx**, so that its terms and conditions may be used by the Parties when contracting for the Services, in accordance with the terms and conditions set out below.

While this Master Agreement creates certain obligations between the parties, it does not create an obligation on the part of THE HOSPITAL to engage The University to provide services, nor does it create an obligation on the part of The University to provide services. Such obligations shall arise only upon the execution of a separate written agreement which shall be in the form of the agreement attached at Appendix 1 to this Master Agreement, including any amendments related to this Master Agreement between The University and THE HOSPITAL which incorporates by reference the terms of this Master Agreement (**Works Request**).

AGREED TERMS

1. DEFINITIONS AND INTERPRETATION

1.1 The following words and phrases shall have the meaning ascribed to them below:

Clinical Trial	means the investigation to be conducted/hosted at THE HOSPITAL in accordance with the Protocol
Data Protection Legislation	means all applicable laws and regulations relating to data protection and privacy in England and Wales as amended from time to time, including the

	Data Protection Act 2018 and (for so long as and to the extent that the law of the European Union has legal effect in the UK) the General Data Protection Regulation (EU) 2016/679.
Intellectual Property	means all inventions, patents, copyrights, work of authorship, design rights, trade names, trade-marks, service marks, slogans (whether any of the same are registered or unregistered), know-how, data base rights (including the copyright of software in any code), and any other industrial or intellectual property and related rights anywhere in the world including applications for the foregoing.
Project Materials	means any of THE HOSPITAL's proprietary materials or information, regardless of the form or how they are stored, provided by THE HOSPITAL to The University for the purposes of completing the Services.
Protocol	means the full description of the Clinical Trial which will be provided to The University with each Work Request;
Services	means the provision of medical imaging services (MRI, MEG, EEG, and fNIRS) by The University staff, using the THE UNIVERSITY IMAGING CENTRE's medical imaging equipment, under an executed Works Request.
Special Terms	shall mean any terms included in a Works Request which deviate from the terms of this Master Agreement.
Sponsor	shall mean the organisation that takes on legal and regulatory responsibility for the ethics, initiation, management and financing of the Clinical Trial.
Works Request	shall mean a written agreement between The University and THE HOSPITAL which incorporates by reference the terms of this Master Agreement, including any amendments related to this Master Agreement, which shall be in the form of the agreement attached at Appendix 1 to this Master Agreement.

- 1.2 Clause, schedule, appendix and paragraph headings shall not affect the interpretation of this Master Agreement.
- 1.3 A **person** includes a natural person, corporate or unincorporated body (whether or not having separate legal personality).
- 1.4 The Schedules shall form part of this Master Agreement and shall have effect as if set out in full in the body of this Master Agreement. Any reference to this agreement includes the Schedule.
- 1.5 Unless the context otherwise requires, words in the singular shall include the plural and in the plural include the singular.
- 1.6 A reference to a statute or statutory provision is a reference to it as it is in force for the time being, taking account of any amendment, extension, or re-enactment, and includes any subordinate legislation for the time being in force made under it.
- 1.7 Any obligation in this Master Agreement on a person not to do something includes an obligation not to agree or allow that thing to be done.
- 1.8 References to clauses and schedules are to the clauses and schedules of this agreement.

2. MASTER AGREEMENT AND WORKS REQUEST

- 2.1 During the term of this Master Agreement, should The University be engaged to, should The University agree to provide the Services, the Parties shall enter into a Works Request under this Master Agreement.
- 2.2 Each Works Request will incorporate by reference the terms of this Master Agreement.
- 2.3 Each Works Request shall be a unique agreement which specifically details the Services to be provided and the associated costs, and shall stand alone with respect to any other Works Request.
- 2.4 If any provisions of a Works Request are in direct conflict with this Master Agreement so that the provisions of both cannot be given effect, the terms of the Works Request shall govern the specific issue.

3. OBLIGATIONS OF THE PARTIES

- 3.1 The University shall use reasonable endeavours to provide access to the Services, as described in the Works Request.
- 3.2 Each Party shall inform the other immediately upon becoming aware of any Serious Breach of the Protocol and/or the conditions and principles of ICH-GCP or any other rules, principle or guidance, relating to the Services. A "Serious Breach" is a breach that is likely to affect, to a significant degree:

- (a) the safety or physical or mental integrity of the Clinical Trial participants;
- (b) the scientific value of the Clinical Trial.

3.3 For the avoidance of doubt, The University will not provide any diagnosis or radiological review of Sponsor's data in the course of the provision of any Services.

4. FINANCE

- 4.1 In consideration of the work to be carried out by The University under each Works Request, THE HOSPITAL will pay to The University the sum due under that specific Works Request, including, without limitation, any milestone, price and payment schedule in the Works Request. All sums shall be exclusive of VAT (or equivalent taxes or charges) unless otherwise stated. The University will submit to THE HOSPITAL invoices for the period concerned in accordance with the terms of such Works Request and within 90 days of the End Date. THE HOSPITAL shall pay such invoices within forty-five (45) days of receipt of such invoices.
- 4.2 For the avoidance of doubt, The University reserves the right during the term of this Master Agreement to increase/vary the price of the Services. All prices will be pre-agreed with THE HOSPITAL in writing and subsequently detailed in the relevant Works Request.
- 4.3 If THE HOSPITAL fails to pay any amount under this clause 4 by the due date for payment The University shall be entitled to charge THE HOSPITAL interest thereon payable by THE HOSPITAL forthwith on demand. Such interest shall accrue on a daily basis from the due date to the date of the actual payment at the rate of 3% per annum above the base rate for the time being of **xxxx Bank**.
- 4.4 The costs detailed in each fully signed Works Request will represent full and complete compensation to The University for that specific Work Request and the Services carried out by them. THE HOSPITAL shall be under no obligation to pay The University any amounts that are not detailed in a fully signed Work Request.

5. RESULTS

- 5.1 Any imaging results and associated data generated in the course of the Services (**Results**), shall be the property of THE HOSPITAL or the Sponsor of the Clinical Trial, as appropriate.
- 5.2 Any technology, equipment, inventions, designs, information, know-how, specifications, formulae, data, processes, methods or techniques in existence prior to commencement of the Services and introduced to the work by the Parties and any improvements thereof, including any modifications, derivatives and progeny ("Background IPR") shall remain the property of the Party that introduces it; and shall be available solely for the purpose and duration of the Services. For the avoidance of doubt, Background IPR shall include, but not be limited to, instrument methodologies and techniques. Background IPR will be maintained as confidential by the Parties and will not be disclosed or used to the advantage, either directly or indirectly, of any

company, firm, body or person(s). The obligations imposed by this paragraph will remain binding after the expiry or termination of this Master Agreement.

6. CONFIDENTIAL INFORMATION

- 6.1 Confidential Information shall mean all confidential information (however recorded or preserved) disclosed or made available for the Services, directly or indirectly, to a Party (the Recipient) by the other Party (the Disclosing Party) or its employees, officers, representatives or advisers and marked or identified as confidential at the time of disclosure, but not including any information that:
- (a) is or becomes generally available to the public (other than as a result of its disclosure by the Recipient or its representatives in breach of this agreement), (except that any compilation of otherwise public information in a form not publicly known shall nevertheless be treated as Confidential Information); or
 - (b) was available to the Recipient on a non-confidential basis prior to disclosure by the Disclosing Party; or
 - (c) was, is or becomes available to the Recipient on a non-confidential basis from a person who, to the Recipient's knowledge, is not bound by a confidentiality agreement with the Disclosing Party or otherwise prohibited from disclosing the information to the Recipient; or
 - (d) was lawfully in the possession of the Recipient before the information was disclosed to it by the Disclosing Party as evidenced by written records; or
 - (e) the Parties agree in writing is not confidential or may be disclosed; or
 - (f) is required to be disclosed by virtue of law, regulation or order of a court of competent authority, provided always that reasonable endeavours are made to notify and consult with the Disclosing Party prior to disclosure; or
 - (g) is developed by or for the Recipient independently of the information disclosed by the Disclosing Party.
- 6.2 The Parties agree to maintain the confidential nature of any Confidential Information received under this Master Agreement and not to disclose to any third party any Confidential Information belonging to the other Party or the Sponsor. Each Party undertakes not to make use of any Confidential Information of the other Party other than in accordance with this Agreement, without the prior written consent of the other Party.
- 6.3 Where The University is required to make a disclosure under 6(1)(f) of this Agreement they shall inform THE HOSPITAL within a reasonable time prior to being required to make the disclosure.
- 6.4 Neither Party shall announce publicly or advertise that they are supplying services or undertaking work on behalf of the other Party (or the Sponsor where the Sponsor is not THE HOSPITAL); without the other Party's prior written consent.

7. DATA PROTECTION AND FREEDOM OF INFORMATION

- 7.1 Each Party will comply with all Data Protection Legislation, in respect of any personal data processed in relation to this Agreement. The terms “personal data”, “data controller”, “data processor”, “process”, “processing” and “processed” shall have the meanings given in the Data Protection Legislation.
- 7.2 The Parties acknowledge that for the purposes of the Data Protection Legislation, where THE HOSPITAL is the Sponsor of the Clinical Trial, they will act as the Data Controller of the personal data (and Confidential Information) it shares with The University and The University is the Data Processor. Where the Sponsor is not THE HOSPITAL, THE HOSPITAL will be the Data Processor of the Personal Data it shares for the respective Clinical Trial and The University will act as the Sub-Processor.
- 7.3 Without prejudice to the generality of Condition 7.2, the University shall, in relation to any personal data processed in connection with the performance by the University of its obligations under this Agreement:
- (a) process that personal data only on the written instructions of THE HOSPITAL;
 - (b) ensure that it has in place appropriate technical and organisational measures to protect against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data, appropriate to the harm that might result from the unauthorised or unlawful processing or accidental loss, destruction or damage and the nature of the data to be protected, having regard to the state of technological development and the cost of implementing any measures (those measures may include, where appropriate, pseudo-anonymising and encrypting personal data, ensuring confidentiality, integrity, availability and resilience of its 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 technical and organisational measures adopted by it);
 - (c) ensure that all personnel who have access to and/or process Personal Data are obliged to keep the personal data confidential;
 - (d) not transfer any personal data outside of the European Economic Area without the prior written consent of the University;
 - (e) assist THE HOSPITAL, at THE HOSPITAL's cost, in responding to any request from a data subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;
 - (f) notify THE HOSPITAL without undue delay on becoming aware of a personal data breach;
 - (g) at the written direction of THE HOSPITAL, delete or return personal data and copies thereof to THE HOSPITAL on termination of this Agreement unless required by applicable law to store the personal data; and
 - (h) maintain complete and accurate records and information to demonstrate its compliance with this clause 7.

- (i) Ensure it operates in a way that will safeguard the rights of Data Subjects under the Data Protection Legislation, including, but not limited to, subject access rights, the rights to rectify, port and erase personal data, object to the processing and automated processing of personal data, and restrict the processing of personal data.

7.4 The University may appoint third party processors of personal data under this Agreement only with THE HOSPITAL's prior written consent (such consent not to be unreasonably withheld). The University confirms that where such consent is given, it has entered or (as the case may be) will enter with the third-party processor into a written agreement on terms which are substantially similar to those set out in this clause 7. As between THE HOSPITAL and The University, the The University shall remain fully liable for all acts or omissions of any third-party processor appointed by it pursuant to this clause 7.

7.5 The University will give THE HOSPITAL and any third-party representatives all necessary assistance to conduct audits at no additional cost to THE HOSPITAL. The assistance may include, but is not limited to, physical and remote electronic access to, and copies of records and any other information held at The University's premises, or on systems storing the Personal Data.

7.6 If either Party is subject to a disclosure request pursuant to the Freedom of Information Act (FOIA) 2000 or other applicable legislation or codes of practice then the Party receiving such request shall, where possible, notify the other Party within a reasonable period of time providing the other Party with particulars of the request and such Party shall use reasonable efforts to support the other Party in responding to such request.

8. GOVERNANCE AND COMPLIANCE

8.1 THE HOSPITAL warrants that where the Services are procured in relation to a Clinical Trial or clinical research study, that regulatory and ethical licence, consents and approvals necessary for the conduct of the Clinical Trial or clinical research study have been obtained.

8.2 THE HOSPITAL further warrants that in procuring the Services, it has obtained any consents and approvals necessary to collect and process Personal Data, including consent and approvals for the sub-processing of Personal Data by The University for the purpose of undertaking the Services.

8.3 Each Party warrants that, when performing their obligations under or in connection with this Agreement it will comply with:

- (a) The ICH Harmonised Tripartite Guideline for Good Clinical Practice together with such other good clinical practice requirements as are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to the medicinal products for human use and in guidance published by the European Commission pursuant to such Directive;
- (b) Any applicable study Protocol that THE HOSPITAL has supplied to The University;
- (c) The Human Medicines Regulations 2012;
- (d) The Medicines for Human Use (Clinical Trial) Regulations 2004;

(e) Any other applicable laws and relevant guidance.

9. PROJECT MATERIALS

- 9.1 Where applicable, THE HOSPITAL will be responsible for providing any Project Materials in the quantities necessary for The University to conduct the Services and shall inform The University of any potential hazards of which it has knowledge and which relate to the Project Materials.
- 9.2 The University shall use reasonable endeavours to ensure that any Project Materials provided by THE HOSPITAL are used in accordance with any special conditions specified in the Works Request.

10. WARRANTY AND LIABILITY

- 10.1 Whilst The University will use reasonable endeavours to ensure the accuracy of the Services and any Results, The University makes no warranty, express or implied, as to accuracy and will not be held responsible for any consequence arising out of any inaccuracies or omissions unless such inaccuracies or omissions are the result of negligence on the part of The University or its servants or agents.
- 10.2 No Party shall be liable to another in contract, tort, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement or any Works Request.
- 10.3 The University warrants that it holds a valid insurance policy to cover any claim arising out of the negligent or wilful misconduct of its officers, agents or employees to which this Agreement relates.
- 10.4 The maximum liability of a Party under a Works Request shall not exceed the value of the Works Request and shall not, in any case extend to indirect or consequential losses. Nothing in this Agreement limits or excludes any Party's liability for (a) death or personal injury resulting from negligence; or (b) any fraud or for any sort of other liability which, by law, cannot be limited or excluded.

11. TERM AND TERMINATION

- 11.1 This Master Agreement will come in to effect on **xxxx** and will continue until **xxxx** unless terminated in writing with 1 months' written notice to the other Party. Termination of this Master Agreement shall not affect the validity of any executed Works Requests or the performance of any Services agreed therein.
- 11.2 Each Works Request will come in to effect, and continue for the term, of the dates specified therein.
- 11.3 Either Party may terminate upon 1 months' notice in the event that the other Party is in breach of this Master Agreement and/or a Works Request and such breach has not been rectified or the Party in question has not taken reasonable steps to rectify within 30 days' of notification.

- 11.4 Where termination of this Master Agreement and/or a Works Request is due to circumstances beyond the control of either Party then both Parties shall take all necessary steps to mitigate any further losses howsoever arising from this Agreement.

12. ENTIRE AGREEMENT AND VARIATION

- 12.1 This Master Agreement constitutes the entire agreement between the Parties and supersedes and extinguishes all previous drafts, agreements, arrangements and understandings between them, whether written or oral, relating to its subject matter.
- 12.2 Each Party agrees that it shall have no remedies in respect of any representation or warranty (whether made innocently or negligently) that is not set out in this agreement. Each Party agrees that its only liability in respect of those representations and warranties that are set out in this Master Agreement (whether made innocently or negligently) shall be for breach of contract.
- 12.3 No variation of this Master Agreement shall be effective unless it is in writing and signed by each of the Parties (or their authorised representatives).

13. No WAIVER

Failure to exercise, or any delay in exercising, any right or remedy provided under this Agreement or by law (whether exercised in whole or part) shall not constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict any further exercise of that or any other right or remedy.

14. ASSIGNMENT

Except as otherwise provided in this Master Agreement, no Party may assign, sub-contract or deal in any way with, any of its rights or obligations under this Master Agreement, including any related Works Request, or any document referred to in it.

15. NOTICES

- 15.1 Any notice required to be given under this Master Agreement, shall be in writing and shall be delivered personally, or sent by pre-paid first class post or recorded delivery or by commercial courier, to each Party required to receive the notice at its address as set out below:

(a) University of Xxxxx: Research and Innovation, The University of Xxxxx, Address line 1, Address line 2, Address line 3, POST CODE with a copy to xxxx@xxxx.ac.uk

For the attention of: The Head of Research Contracts

(b) Xxxxx University Hospitals NHS Trust: Research and Innovation, Xxxxx University Hospitals NHS Trust, Address line 1, Address line 2, POST CODE

For the attention of: Xxxxx, Director of Clinical Operations for Research and Innovation, xxxx@nhs.net

or as otherwise specified by the relevant Party by notice in writing to each other Party.

- 15.2 Any notice shall be deemed to have been duly received:
- (a) if delivered personally, when left at the address and for the contact referred to in this clause; or
 - (b) if sent by pre-paid first class post or recorded delivery, at 9.00 am on the second Business Day after posting; or
 - (c) if delivered by commercial courier, on the date and at the time that the courier's delivery receipt is signed.
- 15.3 A notice required to be given under this Master Agreement shall not be validly given if sent by e-mail.

16. No PARTNERSHIP

Nothing in this Master Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between any of the Parties, constitute any Party the agent of another Party, nor authorise any Party to make or enter into any commitments for or on behalf of any other Party.

17. THIRD PARTY RIGHTS

A person who is not a Party to this Master Agreement shall not have any rights under or in connection with it.

18. COUNTERPARTS

This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. A signed copy of this Agreement delivered by e-mailed portable document format file or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

19. GOVERNING LAW AND JURISDICTION

This Agreement shall be governed by and construed in accordance with the laws of England and subject to the exclusive jurisdiction of the courts of England with regard to any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims).

IN WITNESS WHEREOF this Agreement is executed as follows.

Signed by an authorised
representative of **The University of
Xxxxx**

.....

Name:

Title/Position:

Date:

Signed by an authorised
representative of **Xxxxx University
Hospitals NHS Trust**

.....

Name:

Title/Position:

Date:

Appendix 1: Works Request

This Works Request (RIS No. xxxxxxx) is made between:

PARTIES

- (1) The University of Xxxxx of Address line 1, Address line 2, POST CODE, United Kingdom (The University)
- (2) Xxxxx University Hospitals NHS Trust of Address line 1, Address line 2, POST CODE, United Kingdom (THE HOSPITAL)

Each a "Party" and together "the Parties".

BACKGROUND

- A. The University and THE HOSPITAL have entered into a Master Services Rendered Agreement with the effective date of XXXXX (Master Agreement) pursuant to which the The University has agreed to perform certain services for THE HOSPITAL as specified in this Works Request.
- B. This Works Request is entered into pursuant to clause 2 of the Master Agreement.
- C. THE HOSPITAL wishes the University to perform the Services (as set out below) in accordance with the terms of this Works Request (which incorporates the terms of the Master Agreement) [for the purposes of the Clinical Trial entitled '[INSERT TITLE & THE HOSPITAL REF]'].

AGREED TERMS:

1. DEFINITION AND INTERPRETATION

- 1.1 The words, phrases and terms in this Works Request will have the same meaning as those ascribed to them in the Master Agreement.

2. COMMENCEMENT AND EXPIRY

- 2.1 This Works Request shall come in to effect on *Insert Date* ("Commencement Date") and will continue until *Insert Date* ("End Date") when the Services are anticipated to be fully performed, unless terminated earlier pursuant to the Master agreement.

3. MASTER AGREEMENT

- 3.1 This Works Request incorporates the terms of the Master Agreement in accordance with clause 2 of the Master Agreement.

4. WORKS REQUEST

- 4.1 This Works Request shall become a part of, and be performed in accordance with, the terms and conditions of the Master Agreement and any amendments thereto, between The University and THE HOSPITAL.

5. SERVICES

- 5.1 The University shall perform the Services under the terms of the Works Request, as follows:

Insert description of Services as required OR complete table below

<u>Imaging Facilities</u>	<u>Agreed Dates</u>	<u>Total Hours</u>	<u>Cost per hour</u>
<u>Other Facilities</u>			
<u>Other Costs</u>			

6. PROJECT MATERIALS

Insert Description of any Materials supplied by THE HOSPITAL

7. CHARGES AND PAYMENT TERMS

7.1 THE HOSPITAL shall pay The University the fees and disbursements set out in the Invoice Schedule below, in accordance with clause 4 of the Master Agreement, and on the payment times as set out below:

7.2 Invoice Schedule:

Amount	Invoice Date

Invoices for the above payments must be sent to:

XXXXX UNIVERSITY HOSPITALS NHS TRUST

With a copy to xxxxx@nhs.net

****PLEASE NOTE, A PURCHASE ORDER NUMBER WILL BE REQUIRED TO ENSURE RECEIPT OF PAYMENT. ALL PO REQUESTS/QUERIES TO xxxxx@nhs.net. IT IS THE SERVICE PROVIDER'S RESPONSIBILITY TO ENSURE THEY HAVE ACQUIRED A PO NUMBER****

The invoice should include the following reference/information:

RSEARCH & INNOVATION, **[INSERT CI & PROJECT NAME]**

All invoices must be submitted within received six months of the end of the Term of this Agreement. Any invoices received after this period may not be paid.

8. THE UNIVERSITY BANK DETAILS

Bank Name :
VAT Number :

9. SPECIAL TERMS

9.1 Choose an item.

IN WITNESS WHEREOF this Works Request is executed as follows.

Signed by an authorised
representative of **The University of
Xxxxxx**

.....
Name:

Title/Position:

Date:

Signed by an authorised
representative of **Xxxxx University
Hospitals NHS Trust**

.....
Name:

Title/Position:

Date:

Appendix 2: The Prior Agreement