**Final Jan 2023**

**THIS COLLABORATION AGREEMENT ("Agreement")** is dated as of the last date of signature ("**Effective Date**") and is made **AMONG and BETWEEN**:

(1) **IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY & MEDICINE,** whose administrative offices are at Exhibition Road, London SW7 2AZ, UK (hereinafter "**Lead Party" or "Imperial"**)

(2) **Instituto de Estudos para Políticas de Saúde,** whose administrative offices are at Rua Itapeva, 286 cj 81-84, Bela Vista, Sao Paulo, SP, 01332-001, Brazil (hereinafter "**IEPS**")

(3) **National Institute of Public Health of Mexico (INSP**) whose administrative offices are at Avenida Universidad 655, Santa María Ahuacatitlán, 62100 Cuernavaca, Morelos Mexico (hereinafter "**INSP**")

(4) **O.P. Jindal Global University** whose administrative offices are at Sonipat Narela Road, Sonipat, Haryana-131001, India (hereinafter ("**O.P. JGU**")

(5) **Universidad Nacional de Colombia** legally represented by its Rector, Prof. Dr. Dolly Montoya Castaño, named by means of Resolution No 018 of 2021 and Possession Certificate No. 001 of 2021 whose administrative offices are at Carrera 45 No 26 – 85 Edificio Uriel Gutiérrez in the city of Bogotá D. C, Colombia (hereinafter "**UNC")**

(6) **University of York** whose administrative offices are at Heslington, York, YO10 5DD, UK (hereinafter "**York**")

each a "Party" and collectively "the Parties", and

Party 2, Party 3, Party 4, Party 5 and Party 6 are individually referred to as a "Collaborator" and collectively as the "Collaborators".

**WHEREAS**

A. The Lead Party was an applicant in a proposal to the National Institute of Health Research ("the NIHR") for a research project called "**Health Financing Fragmentation and Universal Health Coverage in Brazil, Colombia, Mexico and India** (NIHR150067) ("the Research") as set out in Schedule 1; and

B. The Lead Party has been provided with an NIHR award from the Secretary of State for Health and Social Care ("the Authority") and has received a contract to carry out the Research and this is set out in Schedule 2 ("the Contract"); and

C. The Lead Party wishes the Collaborators to carry out a portion of the Research as envisaged in the proposal and develop the relationship among the Parties.

D. The Project is primarily undertaken for the health and prosperity of low and middle income countries and/or territories as published in the DAC List by OECD from time to time.

This Agreement sets out the terms under which the Parties shall perform the Research:

## 1. DEFINITIONS

1.1 The following expressions shall have the following meanings in this Collaboration Agreement including its recitals, unless the context requires otherwise:

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| **"Applicable Laws"** | means;<br><br>(a) any law, statute, regulation, byelaw or subordinate legislation in force from time to time to which a party is subject and/or in any jurisdiction that the Research is provided to or in respect of;<br><br>(b) the common law and laws of equity as applicable to the parties from time to time;<br><br>(c) any binding court order, judgment or decree;<br><br>(d) any applicable direction, policy, rule or order that is binding on a Party and that is made or given by any regulatory body having jurisdiction over a Party or any of that Party's assets, resources or business. |
| "**Application**" | means the final application dated **18 August 2022** and made by the Lead Party for an NIHR ODA Global Health Research funding award. |
| **"the Authority**" | means the Secretary of State for Health and Social Care of 39 Victoria Street, Westminster, London, England, SW1H 0EU acting as part of the Crown' |
| **"Arising Know How"** | means Know How that is created, devised or generated by or on behalf of the Lead Party, or any of the Collaborators in the course of the performance of the Research. |
| "**Background IP"** | means any Intellectual Property in existence at the Commencement Date or created, devised or generated other than in the performance of the Research and which is actually used in the performance of the Research. |

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| "**Commencement Date**" | means **01 October 2022** notwithstanding the last signature of this Agreement. |
| **'Confidential Information'** | means information of any form, however conveyed and irrespective of the media on which it is stored, that is:<br><br>(a) information which has been designated as confidential by a Party; or<br><br>(b) information that reasonably ought to be considered as confidential including information which relates to the business, affairs, properties, assets, trading practices, goods/services, developments, trade secrets, Intellectual Property, Know How, personnel, customers and suppliers and commercial sensitive information of a Party; or<br><br>(c) Personal Data and/or sensitive personal data within the meaning of the Data Protection Act 2018; or<br><br>(d) the Research Data. |
| **"Commercial Use"** | means any use that supports the generation of revenue including but not limited to:<br><br>(a) any use in support of an application for regulatory approval for a product or service;<br><br>(b) any use in support of the development, promotion or use of a product or service that will be made available on a fee paying basis;<br><br>(c) any use in support of the development, promotion or provision of Health Care direct to an individual on a fee paying basis;<br><br>(d) the provision of a product or a service to any Health Service Provider. |
| "**Completion Date**" | means **30 September 2026** . |
| "**Contract"** | means the contract concluded between the Lead Party and the Authority consisting of the following Sections:<br>Section 1: Form of Contract |

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| | Section 2: Terms and Conditions (including all Schedules)<br>Section 3: Research<br>Section 4: Financial Arrangements<br>Section 5: Key Staff<br>Section 6: Milestone Reporting Schedule |
| "**Crown**" | means the government of the United Kingdom (including the governments of Northern Ireland, Scotland, and Wales), including, but not limited to, government ministers, government departments, government agencies and particular bodies. |
| "**Data Controller**" | has the meaning ascribed to it in the Data Protection Legislation. |
| "**Data Processor**" | has the meaning ascribed to it in the Data Protection Legislation. |
| "**Data Protection Legislation**" | means any Applicable Law relating to processing, privacy, and use of Personal Data, as applicable to the performance of the Research from time to time, including the UK GDPR. |
| "**FOIA**" | means the Freedom of Information Act 2000 and any subordinate legislation made under this Act from time to time together with any guidance and/or codes of practice issued under this Act or by the Information Commissioner in relation to such legislation. |
| "**Foreground IP**" | means any Intellectual Property that is created, generated or developed (whether in whole or in part) during the course of and for the purpose of any part of the Research. For the avoidance of doubt, this:<br>(a) includes Foreground IP generated by or on behalf of the Lead Party or any Collaborator in the course of performing the Research; and<br>(b) excludes Arising Know How and Research Data; and<br>(c) excludes Intellectual Property that has been generated by the Lead Party or any Collaborator without support from the NIHR. |

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| "**Fraud**" | means any offence under English law or equivalent local Applicable laws creating offences in respect of fraudulent acts or at common law in respect of fraudulent acts in relation to the Contract, the facilitation or performance of the Research, or, defrauding or attempting to defraud or conspiring to defraud the Crown. |
| "**Good Industry Practice**" | means standards, practices, methods and procedures conforming to the law and the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged in a similar type of undertaking under the same or similar circumstances. |
| **"Health Care**" | means<br>(a) health care;<br><br>b) health care related services including (without limitation) maintenance or improvement of health via the prevention, diagnosis, treatment, recovery, or cure of disease, illness, injury, and other physical and mental impairments in people, and for evaluation, training and teaching purposes and the promotion, protection, rehabilitation, and provision of palliative care services throughout the course of life; and<br><br>c) preventing disease, prolonging life and promoting health and well-being through the organised efforts of society. |
| "**Health Service Body**" | means<br>a) any institution or organisation (whether governmental, commercial or not for profit) whose primary intent is to promote, restore or maintain health. This includes efforts to influence determinants of health as well as direct health-improving activities, providing health care or health care related services;<br><br>b) any provider of Health Care;<br><br>c) any Social Care Provider;<br><br>in each case in any of (i) the countries listed in the DAC List and/or (ii) the United Kingdom. |

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| "**Imperial Policies"** | means<br><br>(a) Fraud, Bribery and Corruption Policy https://www.imperial.ac.uk/admin-services/secretariat/college-governance/charters/ordinances/finance/<br><br>(b) Equality, Diversity and Inclusion Policies https://www.imperial.ac.uk/equality/governance/policies/<br><br>(c) Modern Slavery - https://www.imperial.ac.uk/finance/purchasing/related-policy-statements/modern-slavery/<br><br>(d) Safeguarding Policy - https://www.imperial.ac.uk/human-resources/compliance-and-immigration/safeguarding/policy-and-code-of-practice-/<br><br>(e) Research Data Management Policy https://www.imperial.ac.uk/research-and-innovation/support-for-staff/scholarly-communication/research-data-management/<br><br>(f) Research Misconduct Policy https://www.imperial.ac.uk/research-and-innovation/about-imperial-research/research-integrity/misconduct/<br><br>(g) Ethics Code https://www.imperial.ac.uk/admin-services/secretariat/secretariat/what-we-do/ethics/ |
| "**Intellectual Property (IP)**" | means all patents, rights to inventions, copyright and related rights, trademarks and trade names, rights to goodwill or to sue for passing off, rights in designs, database rights, rights in confidential information and any other intellectual property rights , in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world. |
| "**IP Policy**" | means the policy to be prepared by the Lead Party and approved by the Authority in accordance with clause 16.1 of the Contract. |

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| **"IATI Standard"** | means the International Aid Transparency Initiative Standard. |
| **"Know How"** | means a package of practical information, resulting from experience and testing, which is:<br>a) secret, meaning not generally known or easily accessible,<br>b) substantial, meaning significant and useful for the production of the contract products, and<br>c) identified, that is to say, described in a sufficiently comprehensive manner so as to make it possible to verify that it fulfils the criteria of secrecy and substantiality" |
| **"LMICs**" | means low and middle income countries and territories as published in the DAC List by OECD from time to time. |
| **"LMIC Joint Lead Investigator"** | means the individual named in Section 5 of the Contract or his/her successor(s). |
| **"NIHR"** | means the UK the National Institute for Health Research |
| **"ODA"** | means Official Development Assistance, including ODA administrative costs, as defined by the OECD from time to time. |
| **"OECD"** | means the Organisation for Economic Co- operation and Development. |
| "**Personal Data**" | has the meaning ascribed to it in the Data Protection Legislation. |
| "**Research Manager**" | shall mean the person appointed by each of the Parties (acting by the Executive Group) from time to time to Research manage the Allocated Work in accordance with this Collaboration Agreement on behalf of that Party. |
| "**Reports**" | means any report, executive summary, paper, abstract or other document provided by a Party in under this Agreement including but not limited to any interim report. For the avoidance of doubt this does not extend to Arising Know How, Research Data, |

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| | Foreground IP or other Intellectual Property described therein. |
| "**Patient, Care User and Public Benefit"** | means achieving any one or more of the following:<br>(a) identifiable improvements in the quality of Health Care or Social Care offered by any Health Service Provider in any LMIC or in the United Kingdom;<br><br>(b) identifiable improvements in the experience of patients receiving by any Health Service Provider in any LMIC or in the United Kingdom;<br><br>(c) identifiable improvements in patient health outcomes;<br><br>(d) identifiable improvements in the efficiency of Health Care, Social Care or Public Health services in any LMIC or in the United Kingdom;<br><br>(e) identifiable and measurable cost savings achieved in any LMIC or in the United Kingdom;<br><br>(f) generating revenue for any Health Service Provider in any LMIC or in the United Kingdom;<br><br>(g) or any other outcome that has been accepted in writing by the Authority and that is designed to benefit any Health Service Provider in any LMIC or in the United Kingdom,<br><br>Except that where the Health Service Provider is a commercial for profit entity, that Health Service Provider may not rely on (d), (e) or (f) above. |
| **"Research Data"** | means information or data which is not Personal Data that is collected or generated in the performance of the Research and includes (but is not limited to) information that is collated or stored in searchable form. For the avoidance of doubt, Research Data does not include information that has been analysed. |
| **"Research"** | means the research task allocated to the Collaborators, as outlined in Section 3 of the Contract. |
| **"Research Period"** | means the period commencing on the Commencement Date and ending on the Completion Date or such later date as may be agreed between the Parties. |

"**UK Joint Lead Investigator**" means the individual named in Section 5 or his/her successor(s).

In this Agreement, references to Clauses and Schedules refer to clauses and schedules of this Agreement unless explicitly stated otherwise, and the singular form of any word includes the plural, and vice versa, as required by the context.

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**THE PARTIES HEREBY AGREE**

## 2. ENTRY INTO THE AGREEMENT

2.1. An entity becomes a Party to this Agreement upon signature of this Agreement by a duly authorised representative.

2.2. This Agreement shall have effect from the Effective Date identified at the beginning of this Agreement.

2.3. An entity joining this Agreement other than through signature by its authorised representative at Clause 20 becomes a Party to the Agreement upon signature of the Accession Document (Schedule 4) by the new Party and the Lead Party. Such accession shall have effect from the date identified in the Accession Document.

## 3. TERM

3.1. This Agreement shall commence on the Commencement Date, and subject to earlier termination in accordance with its terms, shall continue in full force and effect until the Completion Date.

## 4. THE RESEARCH

4.1. The Parties shall undertake the Research, as described in Section 3 of the Contract including any modifications, deletions or expansions approved in writing by all Parties, in accordance with the provisions of this Agreement and in such a way as to enable the Lead Party to comply with the Lead Party's obligations under the Contract. The Parties to this Agreement agree to be bound by the terms and conditions of the Contract, which form part of this Agreement; except that provisions of the Contract that exclusively apply to Lead Party shall apply only to the Lead Party. In the event of any conflict between the terms of this Agreement and the terms of the Contract, then the terms of the Contract will prevail. For the avoidance of doubt, the payment terms agreed between the Lead Party and the Collaborator in a Research Budget Agreement will prevail over the payment terms in clause 4.1 of the Contract.

4.2. Each Party undertakes to take part in the efficient implementation of the Research, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Agreement and as may be reasonably required from it and in a manner of good faith as prescribed by Applicable Law.

4.3. The Research shall be performed by or under the direction and supervision of the LMIC Joint Lead Investigator and the UK Joint Lead Investigator as listed in the Application.

4.4. In respect of the Research, each Party will use its reasonable endeavours to provide adequate facilities; to obtain any requisite materials, equipment and personnel; and to carry out the work diligently and to the highest academic standards, within the scope allowed by its funding. Although each Party will use its reasonable endeavours to perform the Research, no Party undertakes that work carried out under or pursuant to this Agreement will lead to any particular result, nor is the success of such work guaranteed. For the avoidance of doubt, nothing in this Clause purports to permit any Party to reverse engineer or otherwise analyse any of the materials provided to it under this Agreement except in accordance with the provisions of this Agreement and to the extent applicable by Applicable Law.

4.5. In accordance with Clause 3.4 of the Contract, the Parties must ensure that the Research is:

4.5.1. primarily relevant to near-term or long-term benefits to the health or prosperity of low or middle income countries as defined by the OECD from time to time;

4.5.2. performed in accordance with the Authority's policy on the provision of ODA as published and updated from time to time; and

4.5.3. performed and administered in particular (but without limitation) in accordance with the conditions applicable to ODA funding as set out by OECD guidance as published and updated from time-to-time (e.g. Is it ODA? Factsheet November 2008).

4.6. In accordance with Clause 3.8 of the Contract, each Collaborator agrees to comply with or fulfil requirements of the relevant provisions of the Contract and each Collaborator agrees to comply with the IP Policy. Each Collaborator a) acknowledges the terms of the Contract and the IP Policy; b) agrees to assist the Lead Party in complying with the terms of the Contracts and the IP Policy and c) agrees to comply with the aspects of the Contract and the IP Policy that are relevant to the Collaborator.

4.7. If the Lead Party agrees to act as a sponsor for any clinical activity undertaken as part of the Research, the Lead Party may enter into separate clinical study agreements with the other Party or a third party to fulfil regulatory requirements.

4.8. Each Party shall ensure all Research performed by it will be conducted in compliance with Applicable Laws and to a standard equivalent to the UK regulatory regime. No Party shall use or permit any funding provided under this Agreement to be used to support for research performed on animals.

4.9. Each Party shall ensure where clinical activity is to be undertaken that all necessary local ethical and regulatory approvals are in place at the commencement of any work on the Research.

4.10. Each Party undertakes to notify promptly, in accordance with the governance structure of the Research, any significant information, fact, problem or delay likely to affect the Research.

4.11. Each Party shall promptly provide all information reasonably required by the Lead Party or by other Parties to carry out its tasks.

4.12. Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties.

4.13. The Parties shall permit the Authority to conduct a site visit upon request.

4.14. Each Party will comply with all reasonable requests to ensure that the Lead Party is able to comply with the monitoring and reporting requirements of the Contract including but not limited to, the provision of (i) case studies during the Research Period and up to 5 years after the Completion Date and (ii) the final report within 14 days of the Completion Date or early termination of the Agreement.

4.15. Each Party shall, for the duration of the Research, maintain information relating to the gender of their staff and report these to the Authority as requested.

4.16. Each Party shall keep full, detailed and accurate records of all of activities and results obtained in connection with the Research. In this respect, the Parties shall, and shall procure that its staff, any and sub-contractors and their respective staff shall at all times:

4.16.1. observe professional standards; and

4.16.2. comply with the relevant provisions of Clause 37 (Safeguarding Provisions) of the Contract; and

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

4.17. Each Party shall upon request make available to the Authority copies of all records generated in connection with the Research, including for the avoidance of doubt, records generated by employees of the Collaborator, or any employees of other sub-contractors and by any third parties working on the Research.

**RESEARCH MANAGEMENT**

4.18. The Lead Party and Collaborators will agree between themselves to nominate seven (7) individuals to the External Steering Committee to represent the scientific disciplines and country contexts contributing to the Research. Collaborators from the four (4) participating partner regions (Brazil, Colombia, India and Mexico) shall appoint one individual to the Steering Committee to represent the local context. Identification of the nominated individuals shall be done collaboratively by the Parties from the respective

regions. In the unlikely event that a specific region cannot reach agreement over its representative, the UK Joint Lead Investigator will adjudicate. Individuals nominanted to the External Steering Committee should not be directly involved in any of the project activities. Each nominated individual (and any changes thereto) shall be notified in writing to the other Parties. In addition, each Party to this Agreement shall be entitled, but not bound, to appoint an additional individual to the External Steering Committee to act as an observer. An observer appointed in such a manner shall be entitled to attend, but not vote, at meetings of the External Steering Committee.

4.19. The responsibilities of the External Steering Committee are to advise and assist the UK Joint Lead Investigator and LMIC Joint Lead Investigator with:

a) the prioritisation and design of the Research;

b) the implementation, conduct, management, and evaluation of the Research;

c) the dissemination of the results arising from the Research;

d) the review of the proposed amendments to the agreed work plans;

e) the review of the new work plans.

4.20. The quorum for a meeting of the External Steering Committee shall be not less than 50% of the Parties to this Agreement (or their proxies) at least one of whom must have been nominated by the Lead Party and one by a Collaborator.

4.21. **Professor Chris Millet** is hereby appointed as the chair of the External Steering Committee (the “Chair”).

4.22. The External Steering Committee will meet every six (6) months at venues to be agreed or at any time when reasonably considered necessary at the request of any of the Parties. Meetings shall be convened with at least twenty-one (21) days' prior written notice, which notice shall include an agenda. Minutes of the meetings of the External Steering Committee shall be drafted by the Chair and transmitted to the Parties without delay and in any event within fifteen (15) days of the meeting. The minutes shall be considered as accepted by the Parties if, within thirty (30) days from receipt, no Party has objected in writing to the Research Manager. The Research Manager will prepare progress reports as required by the Lead Party and a draft of each report will be circulated to each member of the External Steering Committee along with the written notice for the relevant meeting.

4.23. Each member of the External Steering Committee shall have one vote. Decisions will be taken by a majority vote of a meeting of the External Steering Committee except for those decisions specified elsewhere in the Collaboration Agreement. In the event of a tied vote under this Clause, the Chair shall have the casting vote.

4.24. The Lead Party and Collaborators will form an Internal Steering Group comprised of the lead investigators from each Collaborating Institution in addition to the UK Joint Leader Investigator, LMIC Joint Lead Investigator, and the Research Manager. Changes to any Lead Investigators from each Collaborating party shall be notified in writing to the other Parties. In addition, each Party to this Agreement shall be entitled, but not bound, to

include additional individuals in Internal Steering Group meetings to act as observers and/or contributors. An observer appointed in such a manner shall be entitled to attend, but not vote, at meetings of the Internal Steering Group.

4.25. The responsibilities of the Internal Steering Group are to:

f) provide updates on country-specific and collaborative research activities;

g) review the implementation, conduct, management, and evaluation of the Research;

h) share research plans and outputs between Parties;

i) plan dissemination of the results arising from the Research ;

j) review proposed amendments to the agreed work plans;

4.26. Not used.

4.27. The Internal Steering Group will meet every four (4) to eight (8) weeks at venues to be agreed or at any time when reasonably considered necessary at the request of any of the Parties. Meetings shall be convened with at least twenty-one (21) days' prior written notice, which notice shall include an agenda. Minutes of the meetings of the Internal Steering Group shall be drafted by the Chair and transmitted to the Parties without delay and in any event within fifteen (15) days of the meeting. The minutes shall be considered as accepted by the Parties if, within thirty (30) days from receipt, no Party has objected in writing to the Research Manager. Lead Investigators from each Collaborating Party will prepare progress reports as required by the Lead Party to present at the relevant meeting.

4.28. The Lead Party will appoint a Research Manager.

4.29. The Research Manager will:

4.29.1. attend Steering Committee meetings at the request of the Chair;

4.29.2. be the primary contact for and with the Lead Party and the Authority;

4.29.3. be responsible for the day-to-day management of the Research;

4.29.4. be responsible for financial administration of the Research as required in the Contract;

4.29.5. be responsible for implementing decisions taken by the Director and Steering Committee; and

4.29.6. monitor the progress of the Research with respect to milestones and deliverables.

## 5. PAYMENT

5.1. The Authority has undertaken to provide funding for the Research and the Lead Party shall act as recipient of the funding for the Parties. The sole financial obligation of the Lead Party under this Agreement shall be to forward the payments allocated to the other Parties. The Lead Party and the Collaborator will agree and execute a Research Budget Agreement in the format substantially the same as set out in Schedule 3 of this Agreement prior to any work commencing and prior to any payment being made to the Collaborator.

5.2. In the event that the Authority requires the reimbursement by the Lead Party of any sums paid under this Agreement, then to the extent that such requirement arises from the acts or omissions of a Collaborator, the Collaborator hereby agrees to reimburse the Lead Party the sum received by the Collaboration Party together with any interest charged thereon.

5.3. Each Party shall ensure sound financial management of the funds received under this Agreement and maintain good and accurate records of all expenditure claimed and work undertaken for inspection by or on behalf of the Lead Party or the Authority. In particular, each Party agrees to adhere to clause 4.6- 4.8 of the Contract.

5.4. Each Party agrees to grant the Authority and to any statutory or regulatory auditor of the Authority and to its or their authorised agents the right of reasonable access to (and if necessary to copy) the relevant financial records and/or other information relating to financial records during normal business hours which shall mean 9am -5pm Monday to Friday excluding Bank Holidays as specified by The Bank of England for the duration of the Research Period and for a period of six (6) years after the end of the Research Period.

5.5. If the Lead Party reasonably believes that the Research undertaken or proposed to be undertaken by a Collaborator is deficient or not to the standard described in Schedule 1, it shall formally notify that Party in writing at the earliest possible opportunity, discuss the matter with it and give it clear indications as to how the Research has been deficient. After such discussions, the Collaborator in question shall remedy any agreed faults within an agreed, reasonable time, not generally to exceed twenty one (21) working days unless otherwise agreed. Once the Lead Party has formally notified a Collaborator of any such deficiencies, it shall be entitled to withhold payment of those parts of invoices which relate to the work identified as being deficient. Once the quality of the work has been deemed to be satisfactory (acting reasonably) by the Lead Party, it shall promptly pay any unpaid invoices which remain outstanding.

5.6. Should a Collaborator not be able to remedy the above faults within the period agreed with the Lead Party, the Lead Party shall be entitled to terminate the involvement of such Collaborator from this Agreement. If such a Collaborator feels that the research which it has undertaken is not at fault or that the Lead Party is unfair in its judgement of the quality of the research, and the Lead Party and the Collaborator are unable to agree the matter amicably between themselves, the matter, including, if appropriate, what amounts the Collaborator should be paid for the Research undertaken to date, shall be resolved by the mechanism provided under clause 23.8.

## 6. CONFIDENTIALITY, PUBLICATIONS, PUBLICITY AND BRANDING

6.1. Each receiving Party (the "Receiving Party") hereby undertakes to the disclosing Party (the "Disclosing Party") during the Research Period and five (5) years following the Completion Date:

6.1.1. not to use Confidential Information otherwise than for the purpose for which it was disclosed;

6.1.2. not to disclose Confidential Information to any third party without the prior written consent by the Disclosing Party;

6.1.3. to ensure that internal distribution of Confidential Information by a Receiving Party shall take place on a strict need-to-know basis;

6.1.4. to return to the Disclosing Party on demand all Confidential Information which has been supplied to or acquired by the Receiving Party including all copies thereof and to delete all information stored in a machine readable form. The Receiving Party may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with Applicable Laws and regulations or for the proof of on-going obligations.

6.2. The Receiving Party shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Research as with its own confidential and/or proprietary information, but in no case less than reasonable care

6.3. Each Party shall promptly advise the other Party in writing of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

6.4. No Party shall incur any obligation under clause 6.1 with respect to information which:

6.4.1. is known to the Recipient before the start of the Research Period, and not impressed already with any obligation of confidentiality to the Disclosing Party; or

6.4.2. is or becomes publicly known without the fault of the Receiving Party; or

6.4.3. is obtained by the Receiving Party from a third party in circumstances where the Receiving Party has no reason to believe that there has been a breach of an obligation of confidentiality owed to the disclosing Party; or

6.4.4. is independently developed by the Receiving Party; or

6.4.5. is approved for release in writing by an authorised representative of the Disclosing Party; or

6.4.6. the Receiving Party is specifically required to disclose in order to comply with applicable laws or regulations or fulfil an order of any Court of competent jurisdiction provided that, in the case of a disclosure under the

Freedom of Information Act 2000 or any other Applicable Laws , none of the exemptions in that Act applies to the Confidential Information.

6.5. If any Party receives a request under the Freedom of Information Act 2000 or any other Applicable Laws to disclose any Confidential Information, it will notify and consult with the other Parties. The other Parties will respond within five working (5) days after receiving notice if the notice requests assistance in determining whether or not an exemption in that Act applies.

6.6. Medical Confidentiality

6.6.1. The Parties agree to adhere to the principles of medical confidentiality and data protection in relation to patients involved in the Research. Personal data (as defined in the Data Protection Legislation or Applicable laws) shall not be disclosed save where this is required directly or indirectly to satisfy the requirements of the Research or for the purpose of monitoring or adverse event reporting and subject always to compliance with the Data Protection legislation or Applicable Laws on medical confidentiality.

6.6.2. The Party shall not disclose the identity of patients/subjects to another Party or third parties without prior written consent of the patient/subject except in accordance with the provisions of the Data Protection Legislation and/or Applicable Laws.

6.6.3. The obligations of this Clause 6.6 in respect of Medical Confidentiality shall remain in force without limit in time

**Publications:**

6.7. The Research will form part of the actual carrying out of a primary charitable purpose of the Parties; that is, the advancement of education through teaching and research. There must therefore be some element of public benefit arising from the Research, and this is secured through the following sub-clauses. The Partis shall ensure that any outcome of the Research or the details of the progress of the Research are prepared and submitted in a suitable peer-reviewed journal in accordance with this Clause 6 as soon as is appropriate and in any event no later than one year after the conclusion of the Research.

6.8. Subject to the written consent of the Authority or the Lead Party and in accordance with the terms of the Contract, all employees, students, agents or appointees of the Parties shall be permitted:-

6.8.1. to publish results, jointly where applicable, obtained during the course of work undertaken as part of the Research; and

6.8.2. in pursuance of the Parties' academic functions, to discuss work undertaken as part of the Research in internal seminars and to give instruction within their organisation on questions related to such work.

6.9. All publications arising from the Research shall give due credit to the Parties involved and shall comply with the Authority's policies and guidelines as outlined in Clause 8 of the Contract. Each Party will submit material intended for publication to the Lead Party

in writing not less than thirty (30) days in advance of the submission for publication. The publishing Party may be required to delay submission for publication if in the Lead Party's opinion such delay is necessary in order for the Lead Party to seek patent or similar protection for material in respect of which it is entitled to seek protection, or to modify the publication in order to protect Confidential Information. A delay imposed on submission for publication as a result of a requirement made by the Lead Party shall not last longer than is absolutely necessary to seek the required protection; and therefore shall not exceed six (6) months from the date of receipt of the material by such Party, although the publishing Party will not unreasonably refuse a request from the Lead Party for additional delay in the event that property rights would otherwise be lost. Notification of the requirement for delay in submission for publication must be received by the publishing Party within sixty (60) days after the receipt of the material by the Lead Party, failing which the publishing Party shall be free to assume that the Lead Party has no objection to the proposed publication.

6.10. The Parties acknowledge that the Authority is entitled to publish the Reports provided to the Authority as required under the Contract.

6.11. The Parties must notify the Authority's representative of any intention to issue a press release (whether it will be issued by the Lead Party or any other Party) at least fourteen (14) calendar days prior to any press release issued by it or on its behalf, directly related to the Research or Foreground IP, Arising Know How or Research Data or of matters arising from such Research. The Party shall send one draft copy of the proposed press release to the Authority's representative at least fourteen (14) calendar days before the date intended for release. For the avoidance of doubt this obligation shall continue in full force and effect following expiry of the Research Period.

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

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

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

6.13. The Collaborators shall ensure that any outcome of the Research or details of the progress of the Research are prepared and submitted for publication in a suitable peer-reviewed journal in accordance with Clause 8.9 of the Contract as soon as is appropriate and in any event no later than one year after the conclusion of the Research.

**Publicity and Branding**

6.14. No Collaborator shall make a public statement in particular media announcement or display or by putting on any website or oral presentation to meetings where directly related to Research or Foreground IP, Arising Know How or Research Data or of matters arising from such Research are likely to be reported by the media without the prior

written consent of the Authority. For avoidance of doubt this obligation shall continue in full force and effect following the expiry of the Research.

6.15. Nothing in this Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

6.16. The Parties shall comply with guidance and advice from the Authority on branding and publicity which may be issued from time to time including, but not limited to, permitted use of the NIHR, GHR, and Department of Health brands, names and logos and ensuring all branding references to the GHR are prefixed with the term "NIHR".

## 7. INTELLECTUAL PROPERTY RIGHTS, RIGHTS TO RESEARCH DATA, AND EXPLOITATION OF INTELLECTUAL PROPERTY

7.1. For the avoidance of doubt all Background IP used in connection with the Research shall remain the property of the Party introducing the same. No Party will make any representation or do any act which may be taken to indicate that it has any right, title or interest in or to the ownership or use of any of the Background IP of the other parties except under the terms of this Agreement. Each Party acknowledges and confirms that nothing contained in this Agreement shall give it any right, title or interest in or to the Background IP of the other Parties save as granted by this Agreement.

7.2. Each Party grants the other Parties a royalty-free, non-exclusive licence for the Research Period to use its Background IP for the sole purpose of carrying out the Research. No Party may grant any sub-licence over or in respect of the other's Background IP save as granted under this Agreement.

7.3. Each Collaborator acknowledges that, under the provisions of the Contract, all Foreground IP, Arising Know-How and Research Data which may arise as part of, incidental to or resulting from the Research shall belong to the Lead Party. The Lead Party shall exploit any Research Data, Arising Know How and/or Foreground IP in accordance with the terms of the Contract including, but not limited to Clauses 16 and 17. To enable the Lead to exercise its rights, each Collaborator hereby grants:

7.3.1. to the Lead Party, all necessary rights to use the Collaborator's Background IP and/or Collaborator's Know-How to the extent necessary to enable the Lead Party to exercise those rights to Foreground IP, Arising Know How and Research Data; and

7.3.2. to the Authority, all necessary rights to use the Collaborator's Background IP and/or Collaborator's Know-How to the extent necessary to enable the Authority to exercise those rights to Foreground IP, Arising Know How and Research Data.

7.4. Each Party is hereby granted by the Lead Party a non-exclusive, irrevocable, non-transferable, royalty-free licence to use all Research Data and Foreground IP generated in the course of the Research for academic teaching, research purposes and for non-commercial clinical purposes.

7.5. Each Party will use the Arising Know How in accordance with Clause 9 of the Contract.

7.6. Each Party shall ensure that it secures ownership of all Research Data, Arising Know How and Foreground IP generated by its employees, students and/or agents under the Research.

**Exploitation of Intellectual Property**

7.7. Unless agreed otherwise, the Lead Party shall undertake the timely prosecution and maintenance of all Foreground IP, Arising Know How and Research Data subject always to Authority consent.

7.8. Each Party shall promptly disclose to the Lead Party all Foreground IP, Arising Know How and Research Data generated by it and each Party shall co-operate with the Lead Party, where required, in relation to the preparation and prosecution of patent applications and any other applications relating to Foreground IP, Arising Know How and Research Data.

## 8. EQUIPMENT

8.1. The Parties shall take all practical steps to purchase all materials and equipment required for the Research at a fair and reasonable price. The total amount available for purchasing equipment shall not exceed £5,000 (or local currency equivalent) per item unless prior written consent has been given by the Lead Party and/or the Authority. It is acknowledged that material and equipment must be purchased for the purposes of the Research only and that it may be purchased by and/or for the Lead Party or the Collaborator based in the UK or LMIC. The Authority may inspect the original quotations and invoices issued to the Lead Party or the Collaborator for equipment purchased in connection with the Research and recover any funds provided for the purchase if the Collaborator does not provide this documentation on request.

8.2. At the end of the Research Period, and after the final presentation of the final report required under Clause 14 of the Contract all equipment purchased for use on the Research with funds provided by the Authority shall:

8.2.1. continue to be used for ODA eligible research for which it was originally purchased;

8.2.2. become the property of the Lead Party or the Collaborator as appropriate.

## 9. TRANSFER OF DATA OR MATERIALS

9.1. In the event that any data or materials being shared by a transferring Party (the "Transferor") to a receiving Party (the "Transferee") under this Agreement is subject to any additional regulations due to its level of sensitivity including, without limitation, data protection or export control legislation, the Parties agree to handle such information or

data in an appropriate and legally compliant manner and in the case of personal data as set out in Schedule 7.

9.2. If applicable, any transfer of human tissue samples will be handled in accordance with the provisions of Schedule 6.

9.3. The Transferor shall notify the receiving Transferee of any such sensitivity prior to transfer.

9.4. The Transferee shall procure that it obtains and shall comply with and maintain any necessary consent, approvals or licences in advance of taking receipt of such information or materials.

9.5. For the avoidance of doubt, nothing in this Agreement purports to permit any Party to reverse engineer or otherwise analyse any of the materials provided to it under this Agreement except in accordance with the provisions of this Agreement.

9.6. It is acknowledged and understood by the Parties that the Authority does not support research involving animal experiments and/or the use of animal tissue within the research projects funded by the Authority.

**10. CORRUPT GIFTS OR PAYMENTS**

10.1. The Parties shall not do, and shall use all reasonable efforts to ensure that any other party involved in the facilitation or performance of the Research does not do any of the following (referred to in this Clause as "Prohibited Act(s)")

10.1.1. offer, give or agree to give to any party (including but not limited to individuals, government authorities and corporate entities) any gift or consideration of any kind as an inducement or reward for doing or not doing (or having done or not having done) any act in relation to the obtaining or performance of this or any other contract with the Crown) or the Research, or for showing or not showing favour or disfavour to any person in relation to this or any other contract with the Crown or that relates to the Research; and

10.1.2. enter into this or any other contract relating to the performance of the Research in connection with which commission has been paid or has been agreed to be paid by it or on its behalf, or to its knowledge, unless before that contract is made particulars of any such commission and the terms and conditions of any such agreement for the payment of it have been disclosed in writing to the Authority.

10.2. If the Collaborator, any of their employees, agents or any sub-contractor, or anyone acting on its or their behalf, does any of the Prohibited Acts or commits any offence as the case may be under the UK Bribery Act 2010 or any other Applicable l Laws or equivalent with or without the knowledge of the Lead Party, in relation to this or any other contract with the Crown, the Lead Party shall be entitled:

10.2.1. to terminate the Agreement immediately by giving notice in writing to the Collaborators and recover from the Collaborators the amount of any loss resulting from the termination;

10.2.2. to recover from the Collaborators the amount or value of any such gift consideration or commission; and

10.2.3. to recover from the Collaborators any other loss sustained in consequence of any breach of this Clause, whether or not the Agreement t has been terminated.

10.3. In exercising its rights or remedies under this Clause, the Lead Party, in consultation with the Authority, shall:

10.3.1. act in a reasonable and proportionate manner having regard to such matters as the gravity of the prohibited act, and the identity of the person performing the Prohibited Act, and, the nature of the procedures and precautions previously put in place by the Lead Party to prevent such Prohibited Acts;

10.3.2. reserve the right to consult with an independent third party for advice and consideration of the case;

10.3.3. give all due consideration, where appropriate, to action other than termination of the Contract, including (without limitation to):

(a) requiring the Collaborator to procure the termination of this Agreement or any other a sub-contract where the Prohibited Act is that of a Collaborator or sub-contractor;

(b) requiring the Collaborator y to procure the dismissal or removal from any involvement with any NIHR-funded Research of an employee (whether its own or that of a sub-contractor) where the Prohibited Act is that of such employee.

**11. FRAUD**

11.1. The Parties shall take all reasonable steps, in accordance with Good Industry Practice, to prevent Fraud in connection with the receipt of monies from the Authority by any of the Parties' (including where appropriate its shareholders, members, directors), employees, agents or sub-contractors, or, any other party involved in the facilitation or performance of the Research.

11.2. The Parties shall notify the Lead Party immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.

11.3. If the Lead Party or the Authority receives allegations of Fraud or has reasonable grounds to believe that Fraud has been committed in relation to this or any other contract with the Crown (including the Authority) the Lead Party, in consultation with the Authority, may:

11.3.1. investigate, or appoint a nominee to investigate, allegations received by the Lead Part or the Authority;

11.3.2. terminate the Agreement immediately by giving notice in writing and recover from the Collaborator the amount of any loss suffered by the Authority resulting from the termination, including the cost reasonably incurred by the Authority of making other arrangements for the supply of the Research and any additional expenditure incurred by the Authority throughout the remainder of the Research Period; or

11.3.3. recover in full from the Collaborator any other loss sustained by the Lead Party or the Authority in consequence of any breach of this Clause.

**12. TRANSPARENCY**

12.1 The Parties acknowledge that the Authority has the right to publish the Contract.

12.2. The Parties acknowledge that the Authority supports the requirements of the International Aid Transparency Initiative (lATI Standard) and shall, at the Authority's reasonable request, provide all necessary assistance to enable the Authority to meet the IATI Standard which shall include the provision of all information and data necessary for the transparent, accurate, timely and comprehensive publishing of all data on all activities related to the delivery of development co-operation and humanitarian aid.

12.3 Each Collaborator must i) publish the NIHR ODA global health funding it has received under this Agreement to the IATI registry and ii) use its reasonable endeavour to publish all other ODA funding it has received or been awarded to the IATI registry.

**13. OFFICIAL DEVELOPMENT ASSISTANCE (ODA)**

13.1. The Parties acknowledges that it is the Authority's intention that all monies paid to the Lead Party and in turn to the Collaborator will be properly categorised as ODA by the OECD.

13.2. The Collaborators shall undertake reasonable endeavours to ensure that all monies paid to the Collaborator can properly be categorised as ODA by the OECD.

13.3. The Collaborators shall notify the Lead Party of any concern it has that monies paid to the Collaborator cannot or may not be properly categorised as ODA by the OECD as soon as reasonably practicable.

13.4. If, as a consequence of the Collaborator’s breach or negligent performance or non-performance of this Agreement, monies provided to the Collaborator are not classified as ODA by the OECD, the Collaborator shall repay to the Lead Party or the Authority a sum equal to the amount which the OECD determines is not ODA. The exercise of the right under this clause 13.4 shall not affect the availability of any other remedy (contractual or otherwise) to the Authority.

## 14. EVALUATION

14.1. The Parties shall provide all reasonable co-operation and assistance necessary to allow the Authority to meet the Secretary of State for Health's obligations under the International Development (Official Development Assistance Target) Act 2015 and the International Development (Reporting and Transparency) Act 2006. Such reasonable co-operation and assistance shall include but not be limited to:

14.1.1. the provision of all information requested by the Authority with the scope of the Research;

14.1.2. reasonable access to any of the Parties premises, records, data and to any equipment used (whether exclusively and non-exclusively) in the performance of the Research; and

14.1.3. access to the Parties personnel involved in the Research.

## 15. DUTY OF CARE

15.1. The Parties owe a duty of care to all those employed or retained by the Collaborators (including but not limited to all staff) to perform the Research and is responsible for the health, safety, security of life and property and general wellbeing of such persons and their property.

15.1 Each Party warrants that it has and will throughout the Research Period: (i) carry out the appropriate risk assessment with regard to the performance of the Research; (ii) provide all those employed or retained by the Party (including but not limited to Key Staff) to perform the Research with adequate information, instruction, training and supervision; and (iii) have appropriate emergency procedures in place to ensure that the Research can be performed without damage to the health, safety, security of life and property and general wellbeing of all those employed or retained by the Collaborator (including but not limited to Key Staff) to perform the Research.

15.2 The provision of information of any kind whatsoever by a Party or the Authority to the other Parties shall not in any respect relieve the Party from responsibility for its obligations under this Clause 15. The Party accepts that the positive evaluation of any part of its proposal for the performance of the Research and the execution of this Agreement is not an endorsement by the other Party nor the Authority of any arrangements which the Party has made for the health, safety, security of life and property and wellbeing of all those employed or retained by the Party (including but not limited to Key Staff) to perform the Research.

15.3 The Collaborator acknowledges that the Lead Party and Authority accepts no responsibility for the health, safety, security of life and property and general wellbeing of all those employed or retained by the Collaborator (including but not limited to Key Staff) to perform the Research.

15.4 The Collaborator shall ensure that training and insurance arrangements made to cover all those employed or retained by the Collaborator (including but not limited to Key Staff)

to perform the Research, are reasonable and prudent in all circumstances, including in respect of death, injury or disablement, and emergency medical expenses.

15.5 The costs of any insurance specifically taken out by the Collaborator to support the performance of the Research may be included as part of the management costs of the Research, and must be separately identified in all financial reporting relating to the Research.

15.6 The Collaborator shall for the duration of the Research, maintain information relating to the gender of their staff and report these to the Lead Party and the Authority as requested.

15.7 Each Collaborator, except York, hereby agrees to abide by the Imperial Polices for the duration of the Research.

15.8 York hereby confirms that it has institutional policies equivalent to the Imperial Policies to enable it to comply with the relevant provisions of this Agreement and the Contract.

## 16 ASSIGNMENT

16.1 No Party will sub-contract, transfer or assign the whole or any part of this Agreement without the prior written consent of the other Parties and the Authority, such consent may be subject to such terms and conditions as the Authority may specify not to be unreasonably withheld, denied or delayed.

16.2 A Party that enters into a subcontract or otherwise involves third parties in the performance of the Research remains responsible for such third party's acts and omissions and as though they were its owns.

16.3 Notwithstanding Clause 16.1, the Party shall ensure that, to the extent they are relevant, and where reasonable to do so, the terms of this Agreement are incorporated into any sub-contract to ensure its subcontractors are aware if and adhere to the terms of this Agreement.

## 17 ADDITION OF NEW PARTIES

17.1 New parties may join the Agreement with the agreement of the Lead Party and the Authority and subject to Clause 17.2 by completing the Accession Document set out in Schedule 4.

17.2 New parties shall be bound by the terms of this Agreement and such other conditions as the Steering Committee and/or the Authority may specify.

## 18 WITHDRAWAL

18.1 Any Party (the "Withdrawing Party") may withdraw from the Research upon six (6) months prior written notice to the others, where it considers withdrawal justified on the grounds that no further purpose to the Research would be served by the Withdrawing Party continuing in the Research. Withdrawal by the Withdrawing Party will only take place after discussions with the other Parties and the Authority. Such discussions to

occur within three (3) months of submission by the Withdrawing Party of notice to withdraw, after which the Parties will confirm to the Withdrawing Party the official date of withdrawal ("Date of Withdrawal").

18.2 In the event of withdrawal of a Party, the Lead Party in collaboration with the other Parties will make all reasonable attempts to reallocate the obligations of the Withdrawing Party under this Agreement to another existing Party or a new Party acceptable to the remaining Parties and the Authority provided that such Party agrees to be bound by the terms of this Agreement. If the reason for withdrawal is that the work allocated to the Withdrawing Party is no longer viable, the Lead Party shall discuss with the Authority the re-allocation or reimbursement of funds in accordance with the Contract.

18.3 The Withdrawing Party shall not from the Date of Withdrawal be entitled to recover any of its costs incurred in connection with the Research and shall, from the Date of Withdrawal, comply with any conditions that may be imposed pursuant to Clause 18.1 which shall include (without limitation);

18.3.1 rights granted to the other Parties in respect of the Withdrawing Party's Background Intellectual Property and Know-How shall continue as set out in Clause 7 of this Agreement, subject to the restrictions contained in this Agreement;

18.3.2 all rights acquired by the Withdrawing Party to the Background Intellectual Property of the other Parties shall cease immediately

18.3.3 all rights acquired by the Withdrawing Party to the Foreground IP, Arising Know and Research Date will not apply to the Foreground IP, Arising Know and Research Date generated following the Date of Withdrawal.

## 19 TERMINATION

19.1 A Party (the 'Terminating Party') may terminate its involvement in this Agreement by giving ninety (90) days prior written notice to the Lead Party, who shall immediately notify the Authority of the said Party's intention to terminate, if another Party (the 'Party in Breach') commits a material breach of the terms of this Agreement, or is persistently in breach of this Agreement in such a manner that the Terminating Party is hindered in its ability to carry out its obligations in the Research. The notice shall include a detailed statement describing the breach. If the breach is capable of being remedied and is remedied within the ninety (90) day notice period, then the termination shall not take effect. If the breach is of a nature such that it can be fully remedied but not within the ninety (90) day notice period, then termination shall also not be effective if the Party involved begins to remedy the breach within that period, and then continues diligently to remedy the breach until it is remedied fully. If the breach is incapable of remedy, or a persistent breach, then the termination shall take effect at the end of the ninety (90) day notice period in any event.

19.2 In the event of termination, the Terminating Party shall, however, continue to comply with the obligations under Clause 18.3.

19.3 Without prejudice to any other right or remedy a Party may have, this Agreement may be terminated immediately in the event that the Contract is terminated for any reason, in

which event Schedule 3 shall be amended accordingly and either (i) the Collaborator shall repay to the Lead Party any funds remaining from the amounts paid to it after it has taken into account all expenditure incurred and unavoidable, outstanding, reasonable commitments relating to the Research up to the date of termination, or (ii) the Lead Party shall make payments to the Collaborator to cover expenditure incurred and unavoidable, outstanding, reasonable commitments relating to the Research up to the date of termination which are not covered by the sums received by the Collaborator prior to termination, as the case may be, providing such funding is provided to the Lead Party by the Authority.

19.4 Each Party agrees to notify the other Party promptly if at any time their Key Staff is unable or unwilling to continue the direction and supervision of the Research. Within sixty (60) days after such incapacity or expression of unwillingness that Party shall nominate a successor to replace their key academic. The other Party will not decline unreasonably to accept the nominated successor. However, if the successor is not acceptable on reasonable and substantial grounds, then either (i) such Party will be asked to withdraw from the Research in accordance with Clause 18.2; or (ii) this Agreement may be terminated by the Lead Party giving ninety (90) days' written notice to the other Parties.

19.5 The Lead Party agrees to notify the Collaborators promptly if at any time the LMIC Joint Lead Investigator or the UK Joint Lead Investigator is unable or unwilling to continue the direction and supervision of the Research. Within sixty (60) days after such incapacity or expression of unwillingness the Lead Party or the relevant Collaborator shall nominate a successor to replace the relevant Investigator. The Lead Party shall discuss such nominations with the Authority and will inform the Collaborators of the outcome. However, if the successor is not acceptable to the Authority, then the Lead Party may terminate this Agreement by giving ninety (90) days' written notice to the other Parties.

19.6 The expiration of the Research Period, or the termination of this Agreement under Clauses 19.1, 19.4 or 19.5, shall cause the termination with effect from the date of expiry or termination of the obligations imposed on the Parties under Clause 4.

19.7 In addition to the remedies contained in Clause 18 (Withdrawals); in the event that any Party shall commit any material breach of or default in any terms or conditions of this Agreement, the non-defaulting Parties may by unanimous vote decide to instruct the Lead Party (or in the case of the Lead Party, the Authority) to serve written notice of such breach on the defaulting Party and in the event that such Party fails to remedy such breach within ninety (90) days after receipt of such written notice (where such breach is remediable) the Parties may collectively, at their option and in addition to any other remedies which they may have at law or in equity, and with the approval of the Authority, remove the defaulting Party and continue with the Collaboration Agreement or terminate this Collaboration Agreement. Any removal of the defaulting Party shall be effective as of the date of the receipt of such notice, in respect of a breach incapable of remedy, and, otherwise at the end of the ninety (90) day period referred to above, whereupon the provisions of Clause 18.3 shall apply to the defaulting Party.

19.8 If any Party (a) passes a resolution for its winding-up; or if (b) a court of competent jurisdiction makes an order for that Party's winding-up or dissolution; or makes an administration order in relation to that Party; or if any Party (c) appoints a receiver over,

or an encumbrancer takes possession of or sells an asset of, that Party; or (d) makes an arrangement or composition with its creditors generally; or (e) makes an application to a court of competent jurisdiction for protection from its creditors generally; the remaining Parties shall meet to either suspend or terminate that Party's involvement in the Research. Any removal of the defaulting Party shall be effective as of the date of the receipt of such notice whereupon the provisions of Clause 18.3 shall apply to the defaulting Party.

19.9 In the event that it is agreed by all the Parties and the Authority that there are no longer valid reasons for continuing with the Research the Parties may decide by unanimous vote to terminate this Agreement. In the event of such termination each Party shall be reimbursed for all costs and non-cancellable commitments properly charged in accordance with this Agreement and incurred or committed up to the date of termination, providing that such funds have been or are able to be recovered from the Authority. For the avoidance of doubt, no Party shall be required to contribute to any losses suffered by another Party in circumstances where costs have not been recovered from the Authority.

19.10 Termination or expiry of the Agreement shall not affect the survival of any clauses or provisions herein which are stated, or which by their nature are intended, to continue after termination or expiry.

19.11 Upon termination of this Agreement, each Party shall use reasonable efforts to return all property including the confidential information and Background Intellectual Property received from the other Parties under this Agreement, whether in hard copy, electronic form, or other media unless such continue use is explicitly permitted hereunder.

## 20 LIMITATION OF LIABILITY

20.1 No Party makes any representation or warranty that advice or information given by any of its employees, students, agents or appointees who work on the Research, or the content or use of any materials, works or information provided in connection with the Research, will not constitute or result in infringement of third-party rights.

20.2 No Party accepts any responsibility for any use which may be made of any work carried out under or pursuant to this Agreement, or of the results of the Research, Intellectual Property nor for any reliance which may be placed on such work or results, Intellectual Property nor for advice or information given in connection with them.

20.3 The Parties undertake to make no claim in connection with this Agreement or its subject matter against any employees, students, agents or appointees of the other Parties (apart from claims based on fraud or wilful misconduct). This undertaking is intended to give protection to individual researchers: it does not prejudice any right which a Party might have to claim against any other Party.

20.4 The liability of any Party for any breach of this Agreement, or arising in any other way out of the subject-matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.

20.5 The Lead Party has made a number of indemnities to the Authority as detailed in the Contract. The Collaborator hereby indemnifies the Lead Party in respect of any claims

made by the Authority against the Lead Party due to the actions or omissions of the respective Collaborator.

20.6 Except for the indemnity given in Clause 20.5 and except for any liability arising from the wilful act or negligence of a Party, the maximum liability of a Party under or otherwise in connection with this Agreement or its subject matter shall not exceed the monies received by that Party under this Agreement as detailed in Schedule 3.

20.7 Nothing in this Agreement limits or excludes any Party's liability for:

20.7.1 death or personal injury resulting from negligence; or

20.7.2 any fraud or for any sort of other liability which, by law, cannot be limited or excluded.

20.8 If any sub-clause of this Clause 20 is held to be invalid or unenforceable under any applicable statute or rule of law then it shall be deemed to be omitted, and if as a result any Party becomes liable for loss or damage which would otherwise have been excluded then such liability shall be subject to the remaining sub-clauses of this Clause 20.

20.9 The terms of this Agreement shall not be construed to amend or limit any Party's statutory liability.

## 21 NOTICES

21.1 The Lead Party's and the Collaborator's representatives for the purpose of receiving legal notices, reports and other notices shall until further notice be as stated in Schedule 5.

## 22 FORCE MAJEURE

22.1 A Party shall not be liable for failure to perform its obligations under this Collaboration Agreement, nor be liable to any claim for compensation or damage, nor be deemed to be in breach of this Collaboration Agreement, if such failure arises from an occurrence or circumstances beyond the reasonable control of that Party.

22.2 If a Party affected by such an occurrence causes a delay of three (3) months or more, and if such delay may reasonably be anticipated to continue, then the Parties shall, in consultation with the Authority, discuss whether continuation of the Research is viable, or whether the Research and this Agreement should be terminated.

## 23 ASSIGNABILITY AND SUBCONTRACTING

23.1 Except as set out in Schedule A in the Contract, no Party shall sub-contract, transfer or assign the whole or any part of this Agreement without the prior written consent of the Authority, which consent may be subject to such terms and conditions as the Authority may specify. Approval of a sub-contractor shall be signified by the inclusion of the name in Schedule A "Approved Collaborators and Sub- Contractors".

23.2 Each Party shall be responsible for the acts and omissions of its sub- contractors as though they were its own.

23.3 Notwithstanding clause 23.1 above, each Party shall ensure that, to the extent that they are relevant, and where reasonable to do so, the terms of this Agreement are incorporated into any sub-contract and that all reasonable steps are taken by it to ensure that its sub-contractors are aware of and adhere to the terms of Agreement.

## 24 GENERAL

24.1 Clause headings are inserted in this Agreement for convenience only, and they shall not be taken into account in the interpretation of this Agreement.

24.2 Nothing in this Agreement shall create, imply or evidence any partnership or joint venture between the Parties or the relationship between them of principal and agent.

24.3 Each Party shall ensure that it has well defined arrangements for investigating and resolving allegations of research misconduct. Where an allegation of research misconduct arises in respect of an individual Party's participation in the Research and leads to a subsequent formal investigation, the relevant Party shall inform Lead Party and the Authority of the investigation and its outcome. Where an allegation of research misconduct arises in respect of several Parties' participation in the Research, the relevant Parties will work together to determine how the allegation will be investigated and reported.

24.4 No Party shall use the name or any trademark or logo of any other Party or the name of any of its staff or students in any press release or product advertising, or for any other commercial purpose, without the prior written consent of the relevant Parties.

24.5 Except as otherwise expressly provided for herein, the Parties confirm that nothing in this Agreement shall confer or purport to confer on any third party any benefit or any right to enforce any term of this Collaboration Agreement for the purposes of the Contracts (Rights of Third Parties) Act 1999. It is acknowledged and agreed by the Parties that all relevant rights, licenses and obligations recorded in the Agreement can be directly enforceable against the appropriate Collaborator by the Authority pursuant to the Contracts (Rights of Third Parties) Act 1999 or any similar or comparable provisions in any territory relevant to the Party or activities pursuant to the Agreement or any alternative mechanisms having equivalent effect.

24.6 This Agreement and its Schedules (which are incorporated into and made a part of this Agreement) constitute the entire agreement between the Parties for the Research and no statements or representations made by any Party have been relied upon by the other in entering into this Agreement. Any variation shall be in writing and signed by authorised signatories for each Party except that individual Research Budget Agreement can executed and amended by the Lead Party and the Collaborator and do not require consent of the other Parties.

24.7 This Collaboration Agreement shall be governed by English Law and the English Courts shall have exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this Collaboration Agreement.

24.8 If any dispute arises out of this Agreement the Parties will first attempt to resolve the matter informally through designated senior representatives of each Party to the dispute, who are not otherwise involved with the Research. If the Parties are not able to resolve the dispute informally within a reasonable time not exceeding two (2) months from the date the informal process is requested by notice in writing they will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure.

24.9 If any one or more clauses or sub-clauses of this Agreement would result in this Agreement being prohibited pursuant to any applicable competition law then it or they shall be deemed to be omitted. The Parties shall uphold the remainder of this Agreement, and shall negotiate an amendment which, as far as legally feasible, maintains the economic balance between the Parties.

24.10 This Agreement may be executed in any number of counterparts, each of which when executed (and delivered) will constitute an original of this Agreement, but all counterparts will together constitute the same agreement. No counterpart will be effective until each party has executed at least one counterpart.

**AS WITNESS:**

The Parties have caused this Agreement to be duly signed by the undersigned authorised representatives in as many separate signature pages per Party as there are Parties the day and year first above written.

EXECUTED as an agreement:

**SIGNED** for and on of
**IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY & MEDICINE**

Name: TATIANA PALALIC

Position: -Head, Research Contracts

Signature: DocuSigned by: TATIANA PALALIC 7C6A191497324E3...

Date: 20-Feb-2023

**SIGNED** for and on behalf of
**IEPS**

Name: Miguel Lago

Position: Executive Director

Signature:

Date:

**SIGNED** for and on behalf of
**INSP**

Name: Eduardo Cesar Lazcano Ponce

Position: Director General y Representante Legal del INSP

Signature:

Date:

**SIGNED** for and on behalf of
**O.P. JGU**

Name: Professor Dabiru Sridhar Patnaik

Position: Professor & Registrar

Signature:

Date:

**SIGNED** for and on behalf of
**UNC**

Name: Prof. Dr. Dolly Montoya Castaño

Position: Rector and Legal Representant

Signature:

Date:

**SIGNED** for and on behalf of
**YORK**

Name: Emma Montgomery

Position: Head of Research Grants Operations

Signature:

Date:

**Schedules:**

Schedule 1: The Application
Schedule 2: The Contract
Schedule 3: Research Budget Agreement
Schedule 4: Accession Document
Schedule 5: Notices
Schedule 6: Material Transfer
Schedule 7: Data Protection

## Schedule 1 The Application

## Schedule 2: The Contract

Contract_for_Projec
t_NIHR150067 (2).pd

**Schedule 3:**

## RESEARCH BUDGET AGREEMENT

### template

This Research Budget Agreement is entered into pursuant to, and is subject to the terms of the Agreement dated [insert date]

Name of the Collaborator:

A detailed budget for the proposed work was submitted with the Application and is approved by the Authority.

The Collaborator's allocated budget is as follows:

| **Summary Totals** | **Indexed fEC Total** | **Funding Body Contribution** | **Indexed Total (cash limited)** |
|---|---|---|---|
| **Directly Incurred Costs:**<br>Salaries<br>Consumables<br>Travel & Subsistence<br>Equipment<br>**TOTAL DI COSTS** | | | |
| **Directly Allocated Costs:**<br>Investigators<br>Estates<br>Other Directly Allocated<br>**TOTAL DA COSTS** | | | |
| **Indirect Costs** | | | |
| **Exceptional items** | | | |
| **Total** | **£** | **£** | **£** |

Option 1

The Collaborator shall send invoices quarterly in arrears for actual expenditure incurred in the said quarter. The Lead Party shall pay the Collaborator within thirty (30) days of the receipt of the said invoices, subject always to receipt of funds from the Authority. The final invoice should be sent to the Lead Party within two (2) months of the Completion Date to allow preparation of the final cost statement by the Lead Party.

The invoices must quote the Research Code PA94067 and Purchase Order number (to be confirmed following the execution this Schedule 3) and should be addressed to:

Imperial College of Science Technology and Medicine
Accounts Payable
Finance Office
Exhibition Road
London, SW7 2AZ

Email: apinvoices@imperial.ac.uk

The Collaborator shall **also** send a cost statement at the same time as the submission of the final invoice signed by its authorised representative and summarising income and expenditure for the Research. The cost statement should quote the Research Code and PO and be sent to Ms Nataleen Gould, Grants Manager, (n.gould@imperial.ac.uk).

The Collaborator is required to **report** on spends every three (**3) months** during the first 4 years, then monthly in the final year. Spends will be assessed against allocated budgets, based on time, activity and category.

The Collaborator **may not** vire funds between categories of spend without permission. The Collaborator must **not exceed** the approved total spend for the respective time point, without permission.

Option 2

The Collaborator shall make advanced payments to the Collaborator as follows:

xxxxxx

The Collaborator is required to **report** on spends every three (**3) months** during the first 4 years, then monthly in the final year. Spends will be assessed against allocated budgets, based on time, activity and category.

The Collaborator **may not** vire funds between categories of spend without permission. The Collaborator must **not exceed** the approved total spend for the respective time point, without permission

**Schedule 4 : Accession Document**

**Agreement, version […, YYYY-MM-DD]**

[OFFICIAL NAME OF THE NEW PARTY]

hereby consents to become a Party and Collaborator to the Agreement identified above and accepts all the rights and obligations of a Party and a Collaborator starting [date], subject to acceptance by the Authority of the request for amendment to the CollaborationAgreement to add [the name of the new Party] as a beneficiary from such date.

IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE

hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date], subject to acceptance by the Authority of the request for amendment to the Agreement to add [the name of the new Party] as a party to the Agreement from such date.

This Accession document has been executed in two (2) originals to be duly signed by the undersigned authorised representatives.

[INSERT NAME OF THE NEW PARTY]
Signature
Name
Title

IMPERIAL COLLEGE OF SCIENCE TEHCNOLOGY AND MEDICINE
Signature
Name
Title
Date

**Schedule 5: Notices**

**Lead Party's** representative for the purpose of receiving reports and other notices shall until further notice be:

For legal notices:

Head, Research Contracts
Joint Research Office
Imperial College London
AHSC Directorate Office
1st Floor, North Corridor
Hammersmith Hospital
Du Cane Road
London, W12 0HS

For Research reports and notifications:

Professor Chris Millet
Imperial College London
Exhibition Road
South Kensington Campus
London
SW7 2AZ

**IEPS's** representative for the purpose of receiving reports and other notices shall until further notice be:

For legal notices:

Maria Cristina Trousdell Franceschini

Rua Itapeva, 286 cj 81-84, Bela Vista, Sao Paulo, SP, 01332-001, Brasil

cristina.franceschini@ieps.org.br

For Research reports and notifications:

Dr. Rudi Rocha

Rua Itapeva, 286 cj 81-84, Bela Vista, Sao Paulo, SP, 01332-001, Brasil

rudi.rocha@ieps.org.br

**INSP's** representative for the purpose of receiving reports and other notices shall until further notice be:

For legal notices:

Elizabeth Robles Carvajal
Jefe de departamento del CISS/Enlace administrative
Avenida Universidad 655 Col. Santa María Ahuacatitlan.
Cuernavaca, Morelos, México. C.P. 62100
Tel: 52 777 3293000 ext. 5117 y 5108

For Research reports and notifications:

Octavio Gomez Dantes
CENTRO DE INVESTIGACIÓN EN SISTEMAS DE SALUD (CISS)
Avenida Universidad 655 Col. Santa María Ahuacatitlan.
Cuernavaca, Morelos, México. C.P. 62100
Tel: 01777 1359628

**O.P. JGU's** representative for the purpose of receiving reports and other notices shall until further notice be:

For legal notices:

Professor Dabiru Sridhar Patnaik,
Professor & Registrar registrar@jgu.edu.in
O.P. Jindal Global [Institution of Eminence Deemed to be University],
Sonipat Narela Road,
Sonipat, Haryana-131001, India

For Research reports and notifications:
Indranil Mukhopadhyay
O.P. Jindal Global [Institution of Eminence Deemed to be University],
Sonipat Narela Road,
Sonipat, Haryana-131001, India

**UNC's** representative for the purpose of receiving reports and other notices shall until further notice be

For legal notices:

Dolly Montoya Castaño,
President,
30 No. 45-03
Building 471 - Office 219.
Bogotá D. C, Colombia

For Research reports and notifications:

Giancarlo Buitrago, gbuitragog@unal.edu.co

**YORK's** representative for the purpose of receiving reports and other notices shall until further notice be

For legal notices:

Emma Montgomery (emma.montgomery@york.ac.uk),
Head of Research Grants Operations,
Research Grant Operations,
Research, Innovation and Knowledge Exchange,
Ron Cooke Hub, Campus East, Heslington,
York YO10 5GE

For Research reports and notifications:

Rodrigo Moreno Serra (rodrigo.morenoserra@york.ac.uk),
Centre for Health Economics,
University of York,
Heslington, York, YO10 5DD

**Schedule 6 Material Transfer Provisions**

1.1 Where required for the performance of the Research, a Party (the "Providing Party") shall make available human tissue samples ("Materials") to the other Party (the "Receiving Party") for the purposes of undertaking the Research as set out in the Agreement. The Parties agree to comply and procure that all personnel who work with the Materials comply with the following provisions:

1.1.1 The Receiving Party will use the Materials solely for the purpose of the Research within the research group of its recipient scientist and shall not transfer the Materials to any third party.

1.1.2 The Receiving Party will comply fully with all Applicable Laws, rules, regulations, codes of practice, research governance or ethical guidelines, or other requirements of any regulatory authority, that may apply to the use of the Material by the Receiving Party from time to time, including (but not limited to) the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as applicable), the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the Human Fertilisation and Embryology Act 1990 (as amended), the EU Tissues and Cells Directive (2004/23/EC) and Commission Directives 2006/17/EC and 2006/86/EC, The Human Tissue Authority Directions and Codes of Practice, and the Medicines for Human Use (Clinical Trials) Regulations 2004, as updated and amended from time to time and, where relevant, the national implementations of the same. .

1.1.3 The Providing Party or the Receiving Party on an individual transfer basis shall use a courier with suitable skill and experience to safely transport the Materials to the Receiving Party in accordance with all Applicable Laws. The Providing Party will bear the cost of carriage and any necessary insurance. The Providing Party makes no charge for the Materials. Risk in and responsibility for the Materials shall pass to the Receiving Party once it is received from the courier at the Receiving Party's laboratory. If so requested by the Providing Party, the Receiving Party shall provide it with written confirmation of the safe receipt of the Materials promptly after their delivery to the Receiving Party's laboratory.

1.1.4 The Receiving Party understands that the Materials may have hazardous properties, contain infectious agents or pose other health and safety risks. Subject to clause 1.1.6 of this Schedule 6, the Providing Party makes no representations and gives no warranties either express or implied in relation to it: for example (without limitation), no warranties are given about quality or fitness for a particular purpose, or freedom from infection. The Providing Party will not be liable for any use made of the Materials by the Recipient Institution. The Receiving Party will use the Materials in accordance with good laboratory practice standards, all due skill and care and, if applicable, with dignity, sensitivity and respect. The Receving Party will comply with all Applicable Laws, approvals, rules, codes of practice and regulations governing the transportation, storage, use and disposal of the Materials. The Receiving Party warrants that it will only use, or permit the use of the Materials info the purpose of the Research.

1.1.5 Except to the extent prohibited by Applicable Law and subject to clause 1.1.6 of this Schedule 6, the Receiving Party assumes all liability for damages which may arise from its receipt, use, storage or disposal of the Materials. The Providing Party will not be liable to the Receiving Party for any loss, claim or demand made by the Receiving Party or made against the Receiving Party by any other Party, due to or arising from its use, storage or disposal of the Materials by the Receiving Party, except to the extent the law otherwise requires.

1.1.6 The Providing Party warrants that where required by Applicable Laws the Materials has been obtained from humans with the appropriate consent as required by the Human Tissue Act 2004 and with ethical approval and the Providing Party shall be liable for any claims arising due to the breach of this warranty. The Providing Party hereby grants to the Receiving Party a non-exclusive research licence to use the Materials for the purpose of the Research.

1.1.7 The Receiving Party undertakes to store the Materials in accordance with all Applicable Laws and not to attempt to identify or contact the donor of the Materials or to compromise or otherwise infringe the confidentiality of information on the donors and their right to privacy.

1.1.8 The Receiving Party shall immediately discontinue the use of the Materials in the event that ethical approval is withdrawn. Should an individual donor or their next of kin rescind their consent, the Providing Party will require, and the Receiving Party agrees to discontinue using the appropriately identified sample and return or destroy it in accordance with the Providing Party's instructions.

1.1.9 Upon completion of the Research, the Receiving Party shall, at the Providing Party's discretion, either a) promptly return all unused Research Materials or b) destroy all unused Research Materials in accordance with Applicable Laws and provide written confirmation that this has been completed.

## SCHEDULE 7 DATA PROTECTION

Where both parties determine the purpose of the Processing in respect of any Personal Data which is Processed in the course of or for the purpose of the Research, the provisions of this Schedule will apply.

1. Each of the parties will be a Data Controller in relation to those Personal Data and will comply with the following in relation to any Personal Data which it Processes in connection with the Research. Each party will:

1.1. Process that Personal Data in accordance with the Data Protection Legislation, affording to Data Subjects such rights and protections as they have under the Data Protection Legislation;

1.2. Process that Personal Data only for the purpose of carrying out the Research;

1.3. take such technical and organisational measures as may be appropriate to ensure the security of that Personal Data (including by way of example and without limitation, the pseudonymisation and encryption of Personal Data, the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services and the ability to restore the availability and access to Personal Data in a timely manner in the event of a physical or technical incident). Without prejudice to the generality of the foregoing, each party will keep that Personal Data secure from any unauthorised or accidental use, access, disclosure, damage, loss or destruction;

1.4. ensure that access to that Personal Data is limited to those of its employees, staff, officers and agents who need access to the Personal Data for the purposes of the Research and will take reasonable steps to ensure the reliability of such persons which shall include ensuring that such persons understand the confidential nature of the Personal Data, have received appropriate training in data protection prior to their use of the Personal Data and have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;

1.5. not authorise any third party or sub-contractor to Process any Personal Data shared by the other party without (i) the prior written consent of that party and (2) such third party or sub-contractor entering into a contract with it on terms which are substantially the same as the terms set out in this Schedule and, on condition that the Processing of that Personal Data pursuant to such contract shall terminate on the earlier of termination or expiry of this Agreement, the end of the Research or the sharing of Personal Data between the parties no longer being required for the purposes of the Research;

1.6. give the other party such information and assistance as it reasonably requires in order to enable the other party to meet its obligations to Data Subjects, in particular, but without limitation, complying with Data Subjects' requests for access to, information about, and the rectification of, their Personal Data;

1.7. notify the other party immediately should it receive any request or enquiry from any Data Subject in relation to the Personal Data being Processed for the purpose of the Research, give the other party such assistance in dealing with that request or enquiry as it may reasonably request;

1.8. notify the other party immediately of any actual or suspected breach of security which involves that Personal Data or breach of this paragraph 1;

1.9. in respect of any Personal Data breach, notify the other party of the Personal Data breach without undue delay (but in no event later than 12 hours after becoming aware of the Personal Data breach) and provide the other party without undue delay (wherever possible, no later than 24 hours after becoming aware of the Personal Data breach) with such details as the other party reasonably requires regarding the nature of the Personal Data breach (including the categories and approximate numbers of data subjects and protected data records concerned or likely to be concerned), any investigations into such Personal Data breach, the likely consequences of the Personal Data breach and any measures taken, or recommended, to address the Personal Data breach, including to mitigate its possible adverse effects) PROVIDED THAT, (without prejudice to the above obligations), if the party notifying the breach cannot provide all these details within the timeframes set out above, it shall (before the end of such timeframes) provide the other party with reasons for the delay and when it expects to be able to provide the relevant details (which may be phased), and give the other party regular updates on these matters;

1.10. (and will ensure that all persons acting on its behalf) without delay (and in any event within 3 days), at the other party's written request, either securely delete or securely return to the other party all the Personal Data that the other party has shared with it in such form as it requests after the earlier of:

1.10.1 the expiry or termination of this Agreement;
1.10.2 the end of the Research; or
1.10.3 the sharing of the Personal Data in question no longer being required for the purposes of the Research; and

securely delete existing copies (unless storage of any data is required by applicable law and, if so, it will inform the other party of any such requirement);

1.11 promptly (and in any event within two Business Days) inform the other party if it receives a complaint or request relating to either party's obligations under the Data Protection Legislation relevant to this Agreement, including any compensation claim from a data subject or any notice, investigation or other action from any local, national or multinational agency, department, official, parliament, public or statutory person or any government or professional body, regulatory or supervisory authority, board or other body responsible for administering any Data Protection Legislation and provide the other party with full details of such complaint or request; and

1.12 not transfer that Personal Data outside the European Economic Area without first obtaining the other party's written consent.

2. Each party will allow the other party at all reasonable times to inspect and review the steps being taken by it to comply with paragraph 1 above, and will give the other party any assistance which it reasonably requires with that inspection and review.

3. The types of Personal Data that will be shared between the parties during the term of this Agreement are set out in the Annex to this Schedule together with any specific access and Processing restrictions and deletion provisions as agreed and established by the parties (for the avoidance of doubt, any such specific access and Processing restrictions and deletion procedures are without prejudice to the generality of paragraph 1 above). Any shared Personal Data must not be irrelevant or excessive with regard to the purposes of the Research.

4. Without prejudice to any termination rights in this Agreement, if any party is in breach of its obligations under paragraph 1, the other party may suspend any sharing of Personal Data for the purposes of the Research until the breach is remedied.

5. All expressions in this Schedule beginning with a capital letter (and not defined elsewhere in this Agreement) have the meaning given to them in the Data Protection Legislation.

6. The parties will agree to any reasonable amendment to this Schedule to bring it into line with any amendment to or re-enactment of any Data Protection Legislation, in particular, but without limitation, to reflect the European General Data Protection Regulation introduced after the date of this Agreement, or to allow each of the parties to comply with any requirement or recommendation of the Information Commissioner or any other data protection or supervisory authority in relation to the Processing of Personal Data.

7. The provisions in this Schedule will continue in full force and effect for so long as a party is a Data Controller or shares any Personal Data with the other party, notwithstanding the expiry or termination of this Agreement or the completion of the Research.

8. Each party (the Indemnifier) will indemnify the other party (the Indemnified Party) and keep the Indemnified Party fully and effectively indemnified on demand against all costs, claims, demands, expenses and liabilities of any nature arising out of or in connection with any breach by the Indemnifier Party of this Schedule.

**Annex to Schedule 7**

The following types of Personal Data will be shared between the Parties during the term of this Agreement:

**DATA PROTECTION PARTICULARS**

| | |
|---|---|
| **The subject matter and duration of the Processing** | Not applicable at the Commencement Date |
| **Data Processor and Data Controller** | . |
| **The nature and purpose of the Processing** | |
| **The type of Personal Data being Processed** | |
| **The categories of data subjects** | |

**SIGNED** for and on behalf of
**IEPS**

Name: Miguel Lago

Position: Executive Director

Signature: 

Date:

01/25/2023

**SIGNED** for and on behalf of
**INSP**

Name: Eduardo Cesar Lazcano Ponce

Position: Director General y Representante Legal del INSP

Signature: 

Date:

**SIGNED** for and on behalf of
**O.P. JGU**

Name: Professor Dabiru Sridhar Patnaik

Position: Professor & Registrar

Signature: 

Date: 01 Feb 2023

**SIGNED** for and on behalf of
**UNC**

Name: Prof. Dr. Dolly Montoya Castaño

Position: Rector and Legal Representant

Signature:

Date:

Firmado digitalmente por DOLLY MONTOYA CASTAÑO
Fecha: 2023.02.10 11:22:35 -05'00'

**SIGNED** for and on behalf of
**YORK**

Name: Emma Montgomery

Position: Head of Research Grants Operations

Signature: DocuSigned by: Emma Montgomery 88F0203A49FD4EB...

Date: 02.02.2023

DocuSign

## Certificate Of Completion

Envelope Id: 314D4FBE78C94FD99EFC69096DC4368E
Status: Completed
Subject: Complete with DocuSign: NIHR GHRU Partner Agreement Template Chris Millett_Final_Jan2023.pdf, S...
Source Envelope:
Document Pages: 55
Signatures: 1
Envelope Originator:
Certificate Pages: 1
Initials: 0
TATIANA PALALIC
AutoNav: Disabled
t.palalic@imperial.ac.uk
EnvelopeId Stamping: Disabled
IP Address: 81.147.60.128
Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

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20-Feb-2023 | 13:39
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t.palalic@imperial.ac.uk
Location: DocuSign

| Signer Events | Signature | Timestamp |
|---|---|---|
| TATIANA PALALIC<br>t.palalic@imperial.ac.uk<br>-Head, Research Contracts<br>Imperial College London<br>Security Level: Email, Account Authentication (None) | DocuSigned by:<br>  <br>7C6A191497324E3...<br>Signature Adoption: Pre-selected Style<br>Using IP Address: 81.147.60.128 | Sent: 20-Feb-2023 \| 13:42<br>Viewed: 20-Feb-2023 \| 13:42<br>Signed: 20-Feb-2023 \| 13:43<br>Freeform Signing |

**Electronic Record and Signature Disclosure:**
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| In Person Signer Events | Signature | Timestamp |
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| Editor Delivery Events | Status | Timestamp |
|---|---|---|

| Agent Delivery Events | Status | Timestamp |
|---|---|---|

| Intermediary Delivery Events | Status | Timestamp |
|---|---|---|

| Certified Delivery Events | Status | Timestamp |
|---|---|---|

| Carbon Copy Events | Status | Timestamp |
|---|---|---|

| Witness Events | Signature | Timestamp |
|---|---|---|

| Notary Events | Signature | Timestamp |
|---|---|---|

| Envelope Summary Events | Status | Timestamps |
|---|---|---|
| Envelope Sent | Hashed/Encrypted | 20-Feb-2023 \| 13:42 |
| Certified Delivered | Security Checked | 20-Feb-2023 \| 13:42 |
| Signing Complete | Security Checked | 20-Feb-2023 \| 13:43 |
| Completed | Security Checked | 20-Feb-2023 \| 13:43 |

| Payment Events | Status | Timestamps |
|---|---|---|