

Instruction Pages

Throughout this document, some text has been highlighted in yellow. Please review these sections and add in the relevant details.

5 - The Intellectual Property section has been drafted with three options; an NIHR option, Joint Ownership, and sole Ownership of the Results by a Party. The most appropriate option should be selected based on the arrangements for the grant and the other two options deleted. Due to the range of grant terms some modifications may be required to any of these options to fit in with the Research Contract. The Joint Ownership and Sole Ownership options have been adapted from the Brunswick Longform Research Collaboration Agreement, with thanks to the ARMA Brunswick Working Group for providing these.

5.1 – The NIHR view is that improvements to Background IP should be treated as arising IP from the Study. However, this view may vary from Funder to Funder. Suggest that the text in yellow is removed/modified based on Parties preference/Funding terms.

5.8.2 – This additional clause ensures that the Leads use of Arising Know How allows for a transferable and sublicensable right in the course of the Contractors normal activities in compliance with clause 15.3 of the Research Contract.

9.4.4 – This would be required for an NIHR funded Study. For non-NIHR funded Studies, inclusion should be based on the requirements of the Research Contract.

9.6 - Further information on NHS Indemnity schemes can be found at: <https://www.hra.nhs.uk/about-us/news-updates/indemnity-cover-nhs-staff-delivering-research/>

12.2 - The reference to Section 3 should be used for NIHR funded Studies.

12.10 – The Governing Law and courts used may be changed to Scotland or Northern Ireland with agreement from all Parties.

12.13.2 – This clause is optional primarily for NIHR funded Studies. However, should another Funder have similar requirements, then this clause can still be used and the clause reference within it changed.

Schedule 5 – Data Protection – This appendix provides Data Processing terms suitable for a Controller to Processor arrangement only. Should a different relationship (Controller to Controller, Joint Controller) be required, then this appendix should be replaced with the Lead's preferred agreement. For the avoidance of doubt, this appendix should cover the data transfer relevant to the Collaborators only. Data

transfer from a trial site to the Sponsor as dictated by the protocol should be covered by the relevant site agreement.

Schedule 5, Appendix 1 – This table contains example wording that can help guide the information required. This should be reviewed and completed relevant for each Study.

Delete these guidance notes after completing the Agreement.

Research Grant Collaboration Agreement

THIS AGREEMENT (the “Agreement”) datedis made BETWEEN:

- (1) NAME, of ADDRESS (“XXXXX” and the “Lead”);
- (2) NAME, of ADDRESS (“XXXXX” and a “Collaborating Party”)
- (3) NAME, of ADDRESS (“XXXXX” and a “Collaborating Party”);

each a “Party” and collectively “the Parties”.

Background

- A. Following a call by [name of funder], [Funding Stream], [Lead] was successful in its Application (attached at Schedule 2) for funding to undertake a research study entitled “[Study title]” reference number “[Reference number]”, which shall be known for the purposes of this Agreement as the “Study”
- B. [Lead] and the [name of funder] (“Funder”) have entered into an Agreement dated [date] (the “Research Contract”) to undertake the Study which commences on [date].
- C. The Parties to this Agreement were Co-Applicants in the Application submitted to the Funder and wish to collaborate on the Study.
- D. [Lead], in its role as Lead is responsible on behalf of the Parties to the Funder for leading the Study and now wishes to specify and/or supplement as appropriate between the Parties the provisions of the Research Contract, a copy of which is attached as Schedule 1.

1. Definitions

- 1.1 In this Agreement, the following terms and expressions shall have the meanings ascribed to them in the table below:

‘Agreement’	shall mean this agreement and the Schedules, as amended from time to time in accordance with clause 12.8;
‘Application’	shall mean the application to the Funder attached at Schedule 2;
‘Arising Know-How’	shall mean Know How that is created, devised or generated by or on behalf of a Party in the course of the Study.
‘Background Intellectual Property’	any Intellectual Property, data, discoveries, information, techniques, Know-how, software and materials (regardless of the form or medium in which they are

	disclosed or stored) generated other than in the performance of the Study that are owned or otherwise controlled by a Party and provided by that Party for use in the Study before or after the date of this Agreement, except any Results;
'Chief Investigator'	shall mean [insert CI] or any agreed successor who has primary responsibility for the design, conducting and reporting of the Study;
'Co-Applicants'	As set out in the Funding Application (and any agreed successors)
'Commencement Date'	shall mean the date on which the Study is to start/started.
'Confidential information'	<p>shall mean information of any form disclosed by any Party to another Party for use in the Study or under this Agreement, however conveyed and irrespective of the media on which it is stored, that is:</p> <p>(a) information which has been designated as confidential by the disclosing Party at the time of disclosure; or</p> <p>(b) information that reasonably ought to be considered as confidential including but not limited to 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 any Party; or</p> <p>(c) Personal Data and sensitive personal data within the meaning of the Data Protection Act 2018 as amended from time to time; or</p> <p>(d) the Results;</p>
Data Protection Legislation	shall mean all legislation and regulatory requirements in force from time to time in the UK relating to the use of personal data and the privacy of electronic communications, including, without limitation (i) the Data Protection Act 2018 or any successor legislation, and (ii) the retained version of the General Data Protection Regulation (EU) 2016/679, as incorporated into UK law by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419) (the "UK GDPR");
'Drop Dead Date'	shall mean [drop dead date]

'External Funding	shall mean the grant provided under the Research Contract issued by the Funder;
'Funder'	shall mean the [name of funder];
'Good Industry Practice'	shall mean 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;
'Intellectual Property'	shall mean all patents, rights to inventions, copyright and related rights, trademarks, service marks and trade names, rights to goodwill or to sue for passing off, rights in designs, database rights, rights in confidential information (including in know-how) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and continuations, continuations-in-part, divisional applications, renewals or extensions of, such rights or forms of protection which subsist or will subsist now or in the future in any part of the world;
'Joint Results'	shall mean any Results that are generated by two or more Parties jointly and for which it is impossible to segregate each Party's intellectual contribution to the creation of such Results;
'Know-How'	shall mean unpatented technical information (including, without limitation, information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, techniques and specifications, quality control data, analyses, reports and submissions) that is not in the public domain and recorded in any tangible form whatsoever;
Patient Benefit	Shall mean achieving any one or more of the following: 1. identifiable improvements in the quality of treatment and clinical care offered by any health service body; 2. identifiable improvements in the experience of patients receiving care from any health service body; 3. identifiable improvements in patient health outcomes; 4. identifiable improvements in the efficiency of any health service body; 5. identifiable and measurable cost savings in any health service body; 6. generating revenue for any health service body; or 7. any other outcome that has been accepted in writing

	by the Funder and that is designed to benefit any health service body or a significant number of patients receiving health care from any health service body;
'Protocols'	shall mean the protocols developed pursuant to the Study, including any updated versions thereof;
'Research Contract'	shall mean the agreement between [Lead] and the Funder a copy of which is attached to this Agreement at Schedule 1;
'Research Data'	<p>shall mean information or data that is collected, collated or generated in the performance of the Study and includes (but is not limited to) information or data that is presented or stored in searchable form. For the avoidance of doubt Research Data:</p> <ol style="list-style-type: none"> 1. does not include, without limitation information or data that has been analysed as part of the Study; 2. does include, but is not limited to, images;
'Results'	shall mean any Intellectual Property, information, data, techniques, Research Data, results, inventions, discoveries, software and material regardless of the form or medium in which they are disclosed or stored, identified or first reduced to practice or writing in the course of the Study, excluding Background Intellectual Property and Arising Know-How;
'Samples'	means any and all tissue, sera, genotypes, human-related data and images, results of genotyping and other bioassays, plasma and DNA, any progeny, subunits, derivatives, modifications or improvements thereof and includes, but is not limited to, any and all clinical information associated with the Samples, and any and all data, datasets, databases, images and designs supplied by one party to the other as part of this Agreement
'Serious Misconduct'	shall mean any of the following: abuse or harassment of any form (including but not limited to bullying, sexual abuse, sexual harassment, psychological abuse and physical violence); non-consensual or unlawful sexual activity; or, any other form of violence, exploitation or abuse.
'Sponsor'	shall mean the organisation that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project as defined in the UK Policy Framework for Health and Social Care Research. For the purposes of this Agreement and the Study, [Lead] will be the Sponsor;

'Study'	shall mean the research Study as described in more detail in the Application;
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- 1.2 Any reference to a clause or schedule is a reference to a clause or schedule of this Agreement.
- 1.3 Unless expressly stated otherwise words importing the singular shall include the plural and vice versa and words denoting any gender shall include all of them.
- 1.4 Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subordinate legislation made pursuant thereto and any subsequent modification or re-enactment of it.
- 1.5 Headings are included for ease of reference only and are not part of this Agreement for the purposes of construction.
- 1.6 Any undertaking by a Party not to do an act or thing shall be deemed to include an undertaking not to permit or suffer such act or thing to be done by another person.
- 1.7 For the avoidance of doubt, in the event there is conflict between this Agreement and the Research Contract, the Research Contract prevails.

2. The Study

- 2.1 This Agreement is executed on the date stated above [and its provisions shall retrospectively take effect from [date]]. The Agreement will continue until the earlier of the withdrawal of the External Funding or [a fixed term of [xx] years] [the completion of the Study]. This Agreement will remain in full force and effect for the duration of the Study unless terminated early under clause 11, but a Party may withdraw or may be deemed to have withdrawn from the Study in accordance with clause 10 or 11.
- 2.2 [If the Study has not commenced by Drop Dead Date, the Funder will withdraw the offer funding in accordance with the terms set out in the Research Contract. [Lead] shall notify the other Parties if it becomes aware that the Study is unlikely to start by the date mentioned above.]
- 2.3 Each Party individually undertakes to:
 - 2.3.1 carry out the tasks allotted to it in the Application and provide the human resources, materials, facilities and equipment that are designated as its responsibility in the Application or as otherwise provided in Schedule 2 and the Division of Responsibilities in Schedule 4 and;
 - 2.3.2 use reasonable endeavours to obtain all regulatory and ethical licences, consents and approvals necessary to carry out the tasks

allotted to it in the Application or as otherwise provided in Schedule 2 .

- 2.3.3 ensure that its employees and students (if any) involved in the Study: observe the conditions attaching to any regulatory and ethical licences, consents and approvals; keep complete and accurate records of all research, development and other work carried out in connection with the Study and of all Results and observations,.
- 2.4 Each of the collaborating Parties acknowledge [Lead] is the sole contracting Party with the Funder and lead applicant for the External Funding under the Research Contract. In accordance with the Research Contract's terms, [Lead] is required to comply with and ensure the compliance of the Parties with the terms of the Research Contract. On that basis each of the Parties agree and undertake to [Lead] to:
- 2.4.1 carry out the Study in accordance with the Research Contract and shall not knowingly or intentionally commit any act or omission which causes or may cause [Lead] to breach the Research Contract in any way and/or otherwise incur any liability of any nature whatsoever under or otherwise in connection with the Research Contract;
- 2.4.2 be bound mutatis mutandis by the terms and conditions of the Research Contract, which form part of this Agreement; except the provisions of the Research Contract that are particular to [Lead] and shall apply only to [Lead].
- 2.4.3 notify [Lead] in accordance with clause 12.1 immediately if it receives any notice or request from the Funder relating to the Study.
- 2.5 Although each of the Parties will use reasonable endeavours to perform the Study, 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.
- 2.6 The Study shall be performed by or under the direction and supervision of the Chief Investigator and Co-Applicant(s) as set out in the Application.
- 2.7 Each of the Parties warrants to each other Party that it has full power and authority under its constitution, and has taken all necessary actions and obtained all authorisations, licences, consents and approvals, to allow it to enter into this Agreement.
- 2.8 Each Party will provide [quarterly/monthly/bi annual] reports [to the Lead] [at the [NAME OF STUDY OVERSIGHT COMMITTEE] meetings] where required summarising the progress of the Study and the Results.

[The following clauses will be specific to each study and the oversight committees required]

- 2.9 The Lead shall ensure establishment of the study oversight committees (to include the [specific committees] (and any other oversight committee) to oversee the progress of the Study.
- 2.10 All operational matters relating to the Study shall be decided upon by the [Committee Acronym] which shall also put in place any structure to manage the Study that it agrees.
- 2.11 [Chief investigator] shall be appointed as the Chair of the [Committee Acronym], or such other individual as the Parties may agree. The Co-Applicants shall be members of the [Committee Acronym].
- 2.12 The [Committee Acronym] shall meet regularly at venues to be agreed (or by teleconference) or at any time when reasonably considered necessary at the request of any of the Parties. The date and agenda for the following meeting shall be set at the previous [Committee Acronym] meeting, confirmation of which shall be sent to the [Committee Acronym] representatives. Minutes of the meetings of the [Committee Acronym] shall be drafted by [post/role] and transmitted to the [Committee Acronym] representatives. The minutes shall be considered as accepted by the Parties if, within thirty (30) days from receipt, no Party has objected in writing.
- 2.13 Additional members may be added to the [Committee Acronym] from time to time where necessary
- 2.14 Should the [Committee Acronym] fail to agree on a significant matter, the issue will be deferred until the next meeting at which it will be voted on. Decisions shall be taken by a majority vote. In the event of a tied vote under this Clause, the Chair shall have the casting vote. The quorum for a meeting of the [Committee Acronym] shall be not less than 50% of the Co-Applicant institutions (or their proxies).
- 2.15 The [Committee Acronym]:
- 2.15.1 Will have a charter which sets out the roles and responsibilities of the group and will advise on recruitment strategies, monitor progress with recruitment, check adherence to the protocol and exercise ethical and data management oversight;
- 2.15.2 will have the power to recommend the Study is halted or terminated in the interests of patient safety or in the interests of wider public health.
- 2.16 No additional person may become a party to this Agreement without the written agreement of all the then existing Parties to this Agreement and the Funder and, subject to the additional party being bound by terms substantially similar to this Agreement and such other conditions as [Lead] or the [Committee Acronym] may specify.

3. Research Governance

3.1 The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to a Party as a consequence of this Agreement or arising from its or their performance of the Study. To the extent applicable to their respective obligations, the Parties agree to comply with the following:

- 3.1.1 The UK Policy Framework for Health and Social Care Research 2017;
- 3.1.2 The Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006;
- 3.1.3 The Mental Capacity Act 2005;
- 3.1.4 The Data Protection Legislation;
- 3.1.5 ICH Harmonised Tripartite Guideline for Good Clinical Practice E6;
- 3.1.6 Orders, rules and requirements made by governmental or regulatory bodies having the force of law (including applicable directions received from a regulatory authority and/or ethics committee)

as may be updated or amended from time to time.

3.2 [Lead] may, on reasonable notice, monitor and audit the conduct of any work conducted under this Agreement of the Parties relating to the Study including the right to inspect, during office hours, any facilities being used for the work conducted under this Agreement and to examine any procedures or necessary records relating to work conducted under this Agreement.

3.3 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 Study and leads to a subsequent formal investigation, the relevant Party shall inform [Lead] and the Funder of the investigation and its outcome. Where an allegation of research misconduct arises in respect of several Parties' participation in the Study, the relevant Parties will work together to determine how the allegation will be investigated and reported.

3.4 Where relevant, the Parties will transfer all Samples relevant to the Study to the other party in good time to allow for the other party to fulfil its obligations under this Agreement subject to the completion by the Parties of the 'Material Information Form for the Transfer of Human Material' as set out in Schedule 6. The lab working on the materials will be expected to comply with all relevant legislation, including the Medicines for Human Use (Clinical Trials) Regulations SI 2004/1031 as amended from time to time.

4. Price and Payment

4.1 The Funder has undertaken to provide the External Funding for the Study and [Lead] shall act as recipient of the External Funding for the Parties in accordance with the Research Contract. The sole financial obligation of [Lead] under this Agreement shall be to forward the External Funding to the Parties, subject to receipt of External Funding, in accordance with Schedule 3 of this Agreement.

- 4.2 Claims for any External Funding will be made in accordance with Schedule 3. Where applicable, each of the Parties will provide sufficient information to [Lead] to allow [Lead] to claim the External Funding and to submit reports to the Funder in accordance with the Funder's requirements from time to time.
- 4.3 Payment will be made by [Lead] to the Parties within 30 days of receipt of a valid invoice, subject always to completion of the Parties tasks as set out in the Application at Schedule 1; subject to clauses 11.3 and 11.6 below; and providing receipt of the External Funding from the Funder.
- 4.4 In the event that the Funder requires reimbursement by [Lead] of any sums paid under the Research Contract, then to the extent that such requirement arises from the acts or omissions of a Collaborating Party, then that Collaborating Party hereby agrees to reimburse [Lead] the relevant sum requested by the Funder and received by that Party, together with any interest charged on it and which [Lead] is obliged to repay to the Funder.
- 4.5 Each Party shall maintain proper financial records relating the Study at all times during the period of the Study and for six (6) years after the end of the Study, and shall provide copies of such records to [Lead] in the event that [Lead] is required to provide the same to the Funder.
- 4.6 The Collaborating Parties will provide to [Lead] a final expenditure statement within two (2) months of the end of the Study..
- 4.7 Equipment purchased by each Party using the External Funding shall be owned by the Party purchasing the relevant equipment, subject to the Funder's requirements as set out in the Research Contract. A Party that uses the External Funding to purchase equipment must retain all quotations and invoices relating to the purchase of equipment until the conclusion of the Study. The Parties agree that a failure to maintain and provide adequate records will be considered a material breach of the Agreement.
- 4.8 In the event that a Party leaves the Study then pursuant to the terms of this Agreement the Party shall refund all advances paid to it except the amount of expended and committed eligible costs as accepted by the Lead and the Funder.
- 4.9 For efficiency, should a Collaborating Party's finance arrangements require modification during the course of the Study, [Lead] shall be entitled to agree a contract amendment with that [Party]/ [Parties] that are subject to the changes only, provided that it does not affect the budgets of any other Collaborating Parties.
- 4.10 In the event that a Party is excluded from the Study due to failure to comply with either this Agreement or the Research Contract or failure to complete the agreed work in an appropriate and timely manner such Party will not be able to recover any additional expenditure incurred as a result of such failure from either [Lead] or any other Party.

5. Intellectual Property Rights and Exploitation

- 5.1 For the avoidance of doubt, this Agreement does not affect the ownership of any Intellectual Property in any Background Intellectual Property or in any other technology, design, work, invention, software, data, technique, Know-how, or materials that are not Results. The Intellectual Property in them will remain the property of the Party that contributes them to the Study (or its licensors). Arising Know-how will remain the property of the Party generating it. No licence to use any Intellectual Property is granted or implied by this Agreement except the rights explicitly granted in this Agreement. [The Parties agree that any improvements or modifications to a Party's Background Intellectual Property arising from the Study which are not severable from that Background Intellectual Property will be deemed to form part of that Party's Background Intellectual Property]
- 5.2 Each Party grants each of the other Parties a non-transferrable, non-sub-licensable, irrevocable, royalty-free, non-exclusive licence for the duration of the Study to use its Background Intellectual Property for the purpose of carrying out the Study, but for no other purpose. If [Lead] requires the use of the Background Intellectual Property of any Collaborating Party in order to exercise its rights in the Results then, provided the Collaborating Party is free to license the Background Intellectual Property in question, the Collaborating Party will not unreasonably refuse to grant or delay granting a licence to [Lead] so that [Lead] may use Background Intellectual Property for the purpose of exercising its rights in the Results, such licence shall be negotiated in good faith and shall be subject to fair and reasonable terms, where appropriate.

[Option 1 - NIHR terms]

- 5.3 In accordance with the Research Contract and subject to the restrictions in clause 6 of the Research Contract, [Lead] will own the Results and shall take such steps, after consultation with the Funder, as may be necessary from time to time to register and maintain any protection for those Results, including filing and prosecuting patent applications and taking any reasonable action in respect of any alleged or actual infringement of those Results. Insofar as the Research Contract allows, [Lead] may commercially exploit the Results in consultation with the other Parties. In such circumstances, [Lead] will pay the other Parties a fair and reasonable royalty rate/revenue on the value of any products or processes commercially exploited by it which incorporate any Results taking into consideration the respective financial and technical contributions of the Parties to the development of the Results, the expenses incurred in securing intellectual property protection thereof and the costs of its commercial exploitation and the proportionate value of the Results in any such product or process. Such arrangements shall be negotiated in good faith and shall be subject to fair and reasonable terms to be agreed between the Parties in a separate agreement.
- 5.4 Where any third party such as a student or contractor is involved in the Study, the Party engaging that third party will ensure that the third party assign to it any Results in order to be able to give effect to the provisions of this clause 5.

- 5.5 To the extent that any Results are capable of prospective assignment, each of the Collaborating Parties hereby assigns those Results to [Lead]; and to the extent that any Results cannot be prospectively assigned, each of the Collaborating Parties will hereby assign such of those Results as it owns to [Lead] as and when those Results are created.
- 5.6 Each of the Collaborating Parties will notify [Lead] promptly after identifying any Results that it believes to be patentable, and will supply [Lead] with copies of those Results. Each of the Collaborating Parties will notify other Results to [Lead] in the quarterly reports provided under clause 2.7.
- 5.7 [Lead] grants each of the Collaborating Parties an irrevocable, non-exclusive, non-transferable, non-sub-licensable, royalty-free licence to use the Results for:
- 5.7.1 the purpose of carrying out the Study;
 - 5.7.2 academic teaching, research purposes and for non-commercial clinical purposes and
 - 5.7.3 for the pursuit of Patient Benefit.
 - 5.7.4 Publication in accordance with clause 6.
- For the avoidance of doubt, as this licence is non-transferable and non-sub-licensable, the licensee is not permitted to grant any rights to use these Results to any third party.
- 5.8 Each of the Parties will use Arising Know-How in accordance with clause 15.3 of the Research Contract. Each of the Parties grants:
- 5.8.1 to the Collaborating Parties: an irrevocable, non-exclusive, non-transferable, non-sub-licensable, royalty-free right to use all Arising Know-How generated in the course of the Research for academic teaching, research purposes and for non-commercial clinical purposes including but not limited to the pursuit of Patient Benefit;
 - 5.8.2 to the Lead: an irrevocable, non-exclusive, transferable, and sub-licensable, royalty-free right to use all Arising Know-How generated in the course of the Research for academic teaching, research purposes and for non-commercial clinical purposes including but not limited to evaluation, teaching and training purposes relating to the provision and commissioning of care and treatment of both NHS patients and NHS funded patients and to achieve to the pursuit Patient Benefit; and.
 - 5.8.3 to the Funder: a non-exclusive, irrevocable, royalty-free, worldwide, sub-licensable licence to use and publish its Arising Know-How in accordance with clause 15.7.1 of the Research Contract.

- 5.9 [In accordance with the terms of the Research Contract] [If the Research Contract requires] , each Party grants the Funder an irrevocable, royalty free, worldwide, non-exclusive, non-transferable, non-sub-licensable licence to use its Background Intellectual Property to the extent that it is necessary to use any information, Intellectual Property, Results, Arising Know-How, materials and conclusions arising from the Study for academic and non-commercial research purposes and for evaluation, teaching and training purposes relating to the provision of care and treatment of both NHS patients and NHS funded patients.

[Option 2 Each Party owns the Results which it generates (non NIHR clauses)]

- 5.3 Subject to clauses 5.1 and 5.4, each Party shall own the Results generated by its employees, students, appointees and agents.
- 5.4 Subject to clause 5.1, Joint Results shall be jointly owned by the Parties who generated such results (the “Joint Owners”) in proportion to their respective intellectual contributions.
- 5.5 The Joint Owners may take such steps as they may decide from time to time, to register and maintain any protection for Joint Results, including filing and prosecuting patent applications for any Joint Results, and taking any action in respect of any alleged or actual infringement of the Joint Results. If one or more of the Joint Owners does not wish to take any such step or action, the other Joint Owner(s) may do so at their expense, and the owner not wishing to take such steps or action will provide, at the expense of the owner making the request, any assistance that is reasonably requested of it.
- 5.6 Any Joint Owner may commercially exploit the Joint Results with the written consent of the other Joint Owner(s) (such consent not to be unreasonably withheld or delayed). In such circumstances, the Joint Owner that is commercially exploiting the Joint Results shall pay the other Joint Owner(s) a fair and reasonable royalty rate/revenue on the value of any products or processes commercially exploited by it which incorporate any Joint Results taking into consideration the respective intellectual and financial contributions of the Joint Owners to the development of the Joint Results, the expenses incurred in securing intellectual property protection thereof, the costs of its commercial exploitation and the proportionate value of the Joint Results in any such product or process.
- 5.7 Subject to any restrictions in Clause 6 (Publication) or any restrictions caused from the transfer of human material or data [and to clauses 11.10 and 11.11 (rights of Leaving Party)][ONLY RELEVANT TO MULTI-PARTY AGREEMENTS - DELETE FOR 2-PARTY AGREEMENTS] each Party grants the other Party(ies):
- 5.7.1 an irrevocable, non-exclusive, non-transferable, non-sub-licensable, royalty-free licence for the duration of the Study to use its Background (provided it is free to license the Background Intellectual Property in question) solely to enable the other Party(ies) to perform their respective parts of the Study; and

- 5.7.2 an irrevocable, non-exclusive, non-transferable, non-sub-licensable, royalty-free licence to use its Results to enable the other Party(ies) to perform their respective parts of the Study, and for academic teaching, research purposes and for non-commercial clinical purposes including but not limited to the pursuit Patient Benefit, [and for academic research projects funded by third parties (including commercial entities)]. For the avoidance of doubt, as this licence is non-transferable and non-sub-licensable, the licensee is not permitted to grant any rights to use these Results to any third party.
- 5.8 Subject to any restrictions in Clause 6 (Publication) or any restrictions caused from the transfer of human material or data [and to clauses 11.10 and 11.11 (rights of Leaving Party)][ONLY RELEVANT TO MULTI-PARTY AGREEMENTS - DELETE FOR 2-PARTY AGREEMENTS], to the extent that exploitation of any Party's Results depends on another Party's Background Intellectual Property, such other Party(ies) shall grant the exploiting Party a non-exclusive licence to use its Background Intellectual Property on fair and reasonable terms to be agreed (provided it is free to licence the Background Intellectual Property in question).

[Option 3: One Party chosen to own and manage Results (non NIHR clause)]

- 5.3 Subject to clause 5.1 and 5.4, all Results shall be owned by the [Lead]. The [Lead] may commercially exploit Results in consultation with the Collaborating Party(ies) who generated the Results. In such circumstances, the [Lead] will pay the relevant Collaborating Party(ies) a fair and reasonable royalty rate/revenue on the value of any products or processes commercially exploited by it which incorporate the Results they generated taking into consideration the respective intellectual and financial contributions of the Collaborating Party(ies) to the development of the Results, the expenses incurred in securing intellectual property protection thereof, the costs of its commercial exploitation and the proportionate value of the Results in any such product or process. The [Lead] shall use all reasonable endeavours to agree such royalty rate/revenue and related payment terms with the relevant Collaborating Party(ies) prior to commencing commercial exploitation.
- 5.4 Subject to any restrictions in Clause 6 (Publication) or any restrictions caused from the transfer of human material or data [and to clauses 11.10 and 11.11 (rights of Leaving Party)][ONLY RELEVANT TO MULTI-PARTY AGREEMENTS - DELETE FOR 2-PARTY AGREEMENTS] each Party grants the other Party(ies) an irrevocable, non-exclusive, non-transferable, non-sub-licensable, royalty-free licence for the duration of the Project to use its Background Intellectual Property (provided it is free to license the Background Intellectual Property in question) solely to enable the other Party(ies) to carry out their respective parts of the Project.
- 5.5 Subject to any restrictions in Clause 6 (Publication) or any restrictions caused from the transfer of human material or data [and to clauses 11.10 and 11.11 (rights of Leaving Party)][ONLY RELEVANT TO MULTI-PARTY AGREEMENTS - DELETE FOR 2-PARTY AGREEMENTS] the [Lead] grants

the Collaborating Party(ies) an irrevocable, non-exclusive, non-transferable, non-sub-licensable, royalty-free licence to use the Results to enable the other Party(ies) to perform their respective parts of the Project and for academic teaching, research purposes and for non-commercial clinical purposes including but not limited to the pursuit Patient Benefit, [and for academic research projects funded by third parties (including commercial entities)]. For the avoidance of doubt, as this licence is non-transferable and non-sub-licensable, the licensee is not permitted to grant any rights to use these Results to any third party.

- 5.6 Subject to any restrictions in Clause 6 (Publication) or any restrictions caused from the transfer of human material or data [and to clauses 11.10 and 11.11 (rights of Leaving Party)][ONLY RELEVANT TO MULTI-PARTY AGREEMENTS - DELETE FOR 2-PARTY AGREEMENTS], to the extent that exploitation of any Results by the [Lead] depends on another Party's Background Intellectual Property, such other Party(ies) shall grant the [Lead] a non-exclusive licence to use its Background Intellectual Property on fair and reasonable terms to be agreed (provided it is free to licence the Background Intellectual Property in question).

6 Publication

- 6.1 [It is a condition of the Research Contract that the Results of the Study be/The Results of the Study will be] published by the Parties in peer reviewed journals acknowledging support from the Funder with [Lead] being responsible to the Funder for the preparation of reports and publications. The first publication of results shall be joint and authorship of the publications shall be in accordance with normal academic practice.
- 6.2 Subject to clause 6.3 and clause 7 below and the terms of the Research Contract, the Parties shall be entitled to publish articles relating to the Study in journals, magazines or other professional publications, or to present papers relating to the Study at seminars or conferences, or on the world-wide web. Subject to clause 6.3 and 7 below and in accordance with normal academic practice, all employees, students, agents or appointees of the Parties (including those who work on the Study) shall be permitted in pursuance of the Parties' academic functions, to discuss work undertaken as part of the Study in seminars and to give instruction within their organisation on questions related to such work. Subject to clause 6.3 and 7 below and in accordance with normal academic practice, all employees, students, agents or appointees of the Parties (including those who work on the Study) shall be permitted to publish Results, jointly where applicable, obtained during the course of work undertaken as part of the Study.
- 6.3 Prior to any publication or presentation (oral or written) the Party intending to present or publish any outcomes of the Study (the "Publishing Party") shall provide a copy of the proposed publication or presentation to [Lead] and each other Party for review (the "Reviewing Party") at least twenty-eight (28) days before the date intended for publication.. The Reviewing Party shall have a period of thirty (30) days from the date of posting of said text in which to intimate, in writing, to the Publishing Party that such text contains Confidential

Information and/or commercially sensitive information or Arising Know-How belonging to that Party, or that the Party wishes to seek intellectual property protection. In the event of any Party intimating that the text contains Confidential Information and/or commercially sensitive information belonging to that Party, the Publishing Party shall accommodate all reasonable requests to amend, redact or delay the publication to the satisfaction of the Reviewing Party, such delay not to exceed three (3) months from the date of submission to the Reviewing Party. In the event of a Party intimating that it wishes to seek intellectual property protection, the Publishing Party shall refrain from publishing or presenting the relevant text for a period of up to three (3) months (or such other reasonable period as may be agreed by the Parties), to allow such protection to be pursued. In the event that the other Parties have received the text and the Publishing Party has received no intimation within the said thirty (30) days, the Publishing Party shall be free to publish and/or present the appropriate text. The provisions of this sub-clause 6.3 shall survive termination or expiry of this Agreement for a period of [three (3) years].

- 6.4 [The Parties agree that, subject to the provisions of clause 7 in respect of Confidential Information and notwithstanding the provisions of clause 5, if the Funder requires it may at any time publish the Report for any non-commercial purpose [NIHR grants only: and in conjunction with their statement on Open Access to research entitled "Statement on DH/NIHR funded research and UK PubMed Central"]. Such purposes may include any entry in a register of research findings or any individual issue of or a review article in a monograph series prepared on the Funder's behalf by any of its staff. The timing of any such publication will be subject to consultation with the Parties and will take account of publication timetables in other peer-reviewed journals and the need to make research findings publicly available as soon as practicable.
- 6.5 Nothing contained in this clause shall be interpreted as preventing the inclusion by a Party or one of its students of some or all the Results in a thesis prepared pursuant to the award of any degree by that Party nor the disclosure in confidence of such thesis to an examiner appointed by that Party nor the lodging in the university library. In the event that such thesis contains Confidential Information, the Publishing Party shall ensure such copy of the thesis to be placed under conditions of restricted access in accordance with that Publishing Party's regulations or for such Confidential Information to be removed before being lodged in the library.
- 6.6 All publications shall acknowledge the Funder and, where appropriate, any other contributing Parties unless requested to the contrary by a Party. [A Publishing Party shall notify the Funder prior to any publication in accordance with condition 17.1 of the Research Contract, including the policy and guidance on publication of research outputs listed in Section 7 of the Research Contract.]

7 Confidentiality

- 7.1 Subject to any obligation of confidentiality in the Research Contract, and subject to the remainder of this clause 7, each Party undertakes to keep secret and strictly confidential any Confidential Information and not disclose to any

third party any Confidential Information nor use for any purpose except to those of its employees, students, directors, officers, advisors or representatives who need to know such information for the purposes of the Study or as expressly permitted by this Agreement, of any other Party.

7.2 None of the Parties shall incur any obligation under clause 7.1 with respect to information which:

7.2.1 is known to the receiving Party before the start of the Commencement Date, and the Receiving Party does not already have an obligation of confidentiality to the disclosing Party; or

7.2.2 is or after disclosure to a Party becomes publicly known without the fault of the receiving Party; or

7.2.3 is obtained by the receiving Party from a third party who has a lawful right to make the disclosure; or

7.2.4 is independently developed by the receiving Party; or

7.2.5 is approved for release in writing by an authorised representative of the disclosing Party; or

7.2.6 the receiving Party is specifically required to disclose in order to fulfil an order of any Court of competent jurisdiction, or is required to disclose by law or regulatory authority provided that, in the case of a disclosure under the Freedom of Information Act 2000 or Freedom of Information (Scotland) Act 2002, the Environmental Information Regulations 2004 or the Environmental Information (Scotland) Regulations 2004, none of the exemptions in those Acts applies to the Confidential Information.

7.3 If any Party receives a request under the Freedom of Information Act 2000 ("FOIA") or the Freedom of Information (Scotland) Act 2002 and the Environmental Information Regulations 2004 ("EIR") or the Environmental Information (Scotland) Regulations 2004 to disclose any Confidential Information, it will notify and consult with the other Parties whose Confidential Information may be threatened with the disclosure. The other Parties will respond within ten (10) working days after receiving notice if the notice requests assistance in determining whether or not an exemption in the EIR and/or FOIA applies. The final decision as to whether any Confidential Information shall be disclosed in response to a request under EIR or FOIA rests with the Party in receipt of the request.

7.4 The obligations of each of the Parties contained in Clause 7 above shall survive expiry or termination of this Agreement [for a further xx years (X) years] [without limit in point of time, as per the Research Contract].

7.5 [The Parties agree that any requests for access to Research Data and Results from third parties of this Agreement will be referred to a Data Management Committee and/or Sponsor. Moreover, no Research Data will be shared with

third parties prior to the primary publication of the results without first consulting with the Funder and executing an appropriate Data Transfer Agreement with the recipient.]

- 7.6 None of the Parties will use any other Party's name or the name of any of the key personnel provided by any other Party, or any other Party's logo in any press release or product advertising, or for any other promotional purpose, without first obtaining that other Party's written consent, without the prior written approval of that Party, subject to terms of the Research Contract, except that each Party may identify the sums received under this Agreement in that Party's annual report and similar publications.

8 Data Protection

- 8.1 Each Party shall comply with applicable Data Protection Legislation and shall ensure that all Personal Data (as defined in the Data Protection Legislation) collected during funding of this Study, if any, will be handled in accordance with applicable Data Protection Legislation including the UK GDPR principles.
- 8.2 Each Party shall comply with the obligations set out in the Data Protection Schedule 5 of this Agreement as appropriate. [or The Parties do not envisage sharing Personal Data (as defined in the Data Protection Legislation). Where Personal Data is shared, an appropriate agreement will be agreed between the Parties.]

9 Liability

- 9.1 No Party makes any representation or warranty in relation to the use of Results, Background Intellectual Property, Intellectual Property, Samples or Arising Know-How. 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, nor for any reliance which may be placed on such work or Results, nor for advice or information given in connection with them. 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 Study, or the content or use of any Results, works or information provided in connection with the Study, will not constitute or result in infringement of third-party rights.
- 9.2 Subject to clause 9.4, 9.8, no Party shall be liable to the others whether in contract, tort (including negligence), for breach of statutory duty, or otherwise, arising under or in connection with the Agreement, the Study and/or the Results for: loss of profit; loss of sales or business; loss of reputation; loss of agreements or contracts; loss of revenues or anticipated savings; loss of or damage to goodwill; loss of use or corruption of software, data or information; any special, indirect or consequential damage of any nature, which arises directly or indirectly from any default on the part of that Party.
- 9.3 Subject to clause 9.4, 9.8, the aggregate liability of each Party to all of the others for any or all breaches of this Agreement, any negligence, or arising in any other way out of the subject matter of this Agreement, the Study or the

Results, will not exceed in total the portion of the External Funding allocated to that Party or £[xxxx], whichever is higher.

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

9.4.1 death or personal injury caused by its negligence;

9.4.2 any fraud or fraudulent misrepresentation;

9.4.3 any sort of liability that, by law, cannot be limited or excluded
[any breach of the Research Contract caused by the negligent acts or omissions of a Party.]

9.5 Each Party that is not an NHS organisation shall throughout the term of this Agreement effect and maintain with a reputable insurance company or underwriters a policy or policies of insurance covering all matters in respect of that Party's activities and shall provide documentary evidence of such insurance on request by any other Party.

9.6 Where a Party is an NHS organisation and is a member of an NHS Indemnity Scheme, it shall maintain its membership therein or otherwise ensure it has appropriate cover against claims arising as a result of clinical negligence.

9.7 The express undertakings and warranties given by the Parties in this Agreement are in lieu of all other warranties, conditions, terms, undertakings and obligations, whether express or implied by statute, common law, custom, trade usage, course of dealing or in any other way. All of these are excluded to the fullest extent permitted by law.

9.8 [Lead] has provided certain indemnities to the Funder in the Research Contract (the "Indemnities"). Subject to Clause 9.2 of this Agreement, each Collaborating Party hereby severally indemnifies [Lead] in respect of any sums paid by [Lead] to the Funder as a result of any claim made by the Funder for which a Collaborating Party is partially or wholly responsible for under any of the Indemnities provided that such Collaborating Party shall only be liable to pay such proportion of the sums related to the acts or omissions of the respective Collaborating Party (or those acting on its behalf) and t the Indemnitees shall (i) mitigate any losses it may suffer or incur in relation to an indemnity provided; (ii) promptly provide notice in writing to the indemnifying Party of any such claim, action or proceeding brought, made or threatened against the Indemnitees; (iii) shall not settle, adjust or compromise such claim, action or proceeding without consultation with the indemnifying Party; and (iv) allow the indemnifying Party to assume control of the claim, action or proceeding, (v) give the indemnifying Party all reasonable assistance (at the indemnifying Party's expense) in dealing with the claim.

9.9 All obligations of and indemnities provided by a Collaborating Party shall be construed severally and in no event shall any Collaborating Party be liable for the acts or omissions of any other Collaborating Party.

10 Force Majeure

- 10.1 In the event that any Party is delayed in the performance of its obligations (except a payment obligation) under this Agreement by an event of Force Majeure, the obligations of the Parties under this Agreement shall remain in suspense until the cause thereof has ceased. "Force Majeure" shall include but not be limited to any of the following: riots, sabotage, acts of war or piracy, destruction of essential equipment by fire, explosion, storm, flood or earthquake, and delay caused by failure of power supplied or transport facilities, pandemic, act of government or any other cause beyond the control of the Parties which renders performance of this Agreement impossible.
- 10.2 No Party shall be liable to any other for any loss including but not limited to any damages or abatement of charges whether directly or indirectly caused or incurred by any failure or delay in the performance of its obligations due to Force Majeure.
- 10.3 If any of the Parties shall become aware of Force Majeure which give or are likely to give rise to any failure or delay on its part, it shall forthwith notify the other by the most expeditious method then available and shall say how long it is estimated that such failure or delay shall continue.
- 10.4 If the delay in performance is more than 3 months, the other Parties may, by written notice, if they unanimously agree to do so, treat that Party as having withdrawn from the Study and the provisions of clauses 11.5 - 11.11 (inclusive) will apply.

11 Term, Termination and Withdrawal

- 11.1 If the duration of the External Funding is revised with the consent of the Funder, the duration of this Agreement shall be amended in accordance with Clause 12.8.
- 11.2 [Lead] may terminate this Agreement by written notice to all other Parties immediately in the event that the Funder terminates the External Funding. [Lead] shall make payments to other Parties to cover expenditure incurred and unavoidable, outstanding and reasonable commitments relating to the Study up to date of termination which are not covered by the sums received by other Party (s) prior to termination, as the case may be, providing such funding is provided to [Lead] by the Funder.
- 11.3 The Lead may terminate this Agreement by immediately by notice in writing without any liability for such termination if i) the regulatory permissions and approvals including without limitation ethical approvals previously granted to perform the Study are withdrawn; or ii) if such regulatory permissions and approvals are not granted and the Parties are unable to agree upon amendments to the Application to obtain the necessary regulatory permissions and approvals.

- 11.4 A Party may terminate its participation in the Study by giving ninety (90) days prior written notice to [Lead] of its intention to terminate on the occurrence of any of the following events:
- 11.4.1 another Party enters into bankruptcy or liquidation or any other arrangement for the benefit of its creditors;
 - 11.4.2 another Party is in material breach of any of its obligations hereunder and such breach is not capable of remedy; or
 - 11.4.3 another Party is in material breach of any of its obligations hereunder and such breach is capable of remedy but the Party remains in breach on the expiry of the ninety (90) day notice period (unless the Party involved begins to remedy the breach within that period, and then continues diligently to remedy the breach until it is remedied fully, in which case the termination shall not be effective).
- 11.5 If they unanimously agree to do so, the other Parties may treat any Party as having withdrawn from the Study with immediate effect by giving written notice to [Lead] if:
- 11.5.1 that Party is in material breach of any provision of this Agreement (including an obligation to make payment) and (if it is capable of remedy) the breach has not been remedied within 30 days after receipt of written notice specifying the breach and requiring its remedy; or
 - 11.5.2 that Party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of its assets, or if it makes any arrangement with its creditors
- and in either case that Party will be deemed to have withdrawn from the Study.
- 11.6 If a Party withdraws or is treated as having withdrawn from the Study in accordance with clause 11.5, the other Parties will use reasonable endeavours to reallocate the obligations of that Party under this Agreement and under the Research Contract amongst themselves or to a third party acceptable to the remaining Parties and the Funder, provided that that third party agrees to be bound by the terms of this Agreement and the Research Contract.
- 11.7 Each Party agrees to notify [Lead] promptly if at any time their key members of staff are unable or unwilling to continue to be involved in the Study. Within thirty (30) days after such incapacity or expression of unwillingness that Party shall nominate a successor to replace any key members of staff. The other Party(s) will not decline unreasonably to accept the nominated successor. However, if the successor is not acceptable on reasonable and substantial grounds, then the other Parties may treat that Party as having withdrawn from the Study.

- 11.8 [Lead] agrees to notify the other Parties promptly if at any time the Chief Investigator is unable or unwilling to continue the direction of the Study. Within thirty (30) days after such incapacity or expression of unwillingness [Lead] shall nominate a successor to replace the Chief Investigator. The Parties will not decline unreasonably to accept the nominated successor. However, if the successor is not acceptable to the Collaborating Parties on reasonable and substantial grounds, then [Lead] may terminate this Agreement by giving thirty (30) days' written notice to the other Parties.
- 11.9 A Party that withdraws or that is treated as having withdrawn from the Study in accordance with clause 11.5 may not recover from any of the other Parties any of its costs incurred in connection with the Study to the extent that those costs were incurred after the date of its withdrawal. In the event that the duration of the Study is extended and a Party no longer wishes to participate in the Study for the period of the extension, the Party may terminate its participation in the Study upon written notice to take effect on the original end date of the Study, subject to that Party having fulfilled its obligations under clause 2.2.
- 11.10 Rights granted under clause 5.2 by a Party that withdraws or that is treated as having withdrawn from the Study in accordance with clause 11.4 and 11.5 to any of the other Parties in respect of the withdrawing Party's Background Intellectual Property will continue for the duration of the Study solely for the purposes of carrying out the Study and will be extended to any new Party to this Agreement, subject to the restrictions contained in this Agreement.
- 11.11 All rights to use any other Party's Intellectual Property granted under this Agreement to a Party that withdraws or that is treated as having withdrawn from the Study in accordance with clause 11.4 will cease immediately excluding under clauses 5.7.2, 5.7.3 and 5.7.4.
- 11.12 In the event of early termination all funding provided by [Lead] under this Agreement that has not been spent or is not subject to an unavoidable commitment to a third party for the purchase of goods or services in furtherance of the Study, shall be returned to [Lead]. Any costs incurred or committed in respect of funds not yet received, shall be reimbursed, subject to receipt from the Funder.

12 General

- 12.1 **Notices:** Any notice to be given under this Agreement must be in writing, may be delivered to the other Party or Parties by any of the methods set out in the left hand column below and will be deemed to be received on the corresponding day set out in the right hand column.

Method of service	Deemed day of receipt
By hand or courier	the day of delivery
By pre-paid first class post	the second Business Day after

	posting
By recorded delivery post	the date of signature of receipt
By email (provided the sender's computer system confirms complete and error-free transmission of that notice to the correct address)	the next Business Day after sending or, if sent before 16.00 (sender's local time) on the Business Day it was sent

The Parties' respective representatives for the receipt of notices are, until changed by notice given in accordance with this clause, as follows:

[Name of Lead]	[Lead Notice address, including email]
[Name of Collaborating Party 1]	[Collaborating Party 1 Notice address, including email]
[Name of Collaborating Party 2]	[Collaborating Party 2 Notice address, including email]
[Add or remove rows as necessary]	

- 12.2 **Assignment:** Except as otherwise provided under this Agreement [and Section 3 of the Research Contact], no Party shall, without the prior written consent of the other Party assign or otherwise transfer partially or totally any of its rights and obligations under this Agreement.
- 12.3 **Illegal/ Unenforceable Provisions:** 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.
- 12.4 **Waiver:** If a Party fails to enforce or delays in enforcing an obligation of any other Party, or fails to exercise or delays in exercising a right under this Agreement, that failure or delay will not affect its right to enforce that obligation or constitute a waiver of that right. Any waiver by a Party of any provision of this Agreement will not, unless expressly stated to the contrary, constitute a waiver of that provision on a future occasion.
- 12.5 **No Agency:** 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.
- 12.6 **Entire Agreement:** 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 Study and no statements or representations made by any Party have been relied upon by the other in entering into this Agreement. Any variation to the Agreement which only

affects the funding levels of the Parties as set out in Schedule 3 shall be valid when agreed in writing by all the Parties directly affected by the variation ('Variation to Funding'). Where a Variation to Funding is signed by the affected Parties, all non-affected Parties shall be given written notice of the Variation to Funding for their information. All other variations to this Agreement require to be signed by all Parties.

- 12.7 **Formalities:** Each Party will take any action and execute any document reasonably requested by any other Party to give effect to any of its rights under this Agreement, or to enable their registration in any relevant territory provided the requesting Party pays the other Party's reasonable expenses of doing so.
- 12.8 **Amendments:** Subject to clause 4.9, this Agreement may be modified only by a written agreement by duly authorised representatives of the Parties.
- 12.9 **Third Parties:** Save for the Funder, 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 Agreement for the purposes of the Contracts (Rights of Parties) Act 1999.
- 12.10 **Governing Law:** This Agreement shall be governed, construed and enforced by the laws of [England and Wales] and the Parties hereby submit to the exclusive jurisdiction of the courts of [England and Wales] for all and any disputes arising out of the terms or subject matter of this Agreement.
- 12.11 **Dispute Resolution:** 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 Study. 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. In the event the Parties cannot resolve by Mediation within a reasonable time not exceeding three (3) months from the date the mediation process is requested by notice in writing, then clause 12.10 shall apply.
- 12.12 **Equality, Anti-Bribery and Modern Slavery:** In carrying out its obligations under this Agreement each Party will:
- 12.12.1 comply with all laws, statutes, regulations, case law and regulatory guidance which apply to it or its activities and which relate to:
 - 12.12.2 anti-bribery and anti-corruption, including the Bribery Act 2010;
 - 12.12.3 equality, including the Equality Act 2010;
 - 12.12.4 modern slavery, including the Modern Slavery Act 2015;
 - 12.12.5 adopt, maintain and follow appropriate policies and procedures to secure such compliance; and

12.12.6 ensure that its employees, students, group companies, subcontractors, agents and their respective employees comply with the terms imposed by these provisions.

[Optional NIHR clause]

12.13 Unlawful Discrimination

12.13.1 Each Party shall ensure that it complies with all current employment legislation and in particular, does not unlawfully discriminate within the meaning of the Equality Act 2010 or any other relevant legislation relating to discrimination in the employment of employees (collectively, the “Employment Legislation”).

12.13.2 [The Parties will enable [Lead] to comply with the requirements of Condition 33.2 of the Research Contract to notify the Funder immediately of any investigation of or proceedings against any individuals involved in the Study under the Employment Legislation where the Parties have knowledge of such investigation or proceedings, and shall cooperate fully and promptly with any requests of the person or body conducting such investigation or proceedings, including allowing access to necessary documents or data required, attending any meetings and providing any information requested]

12.13.3 All Parties shall, and shall use reasonable endeavours to ensure that its employees or agents and/or sub-contractors shall, at all times, act in a way which is compatible with the Convention rights with the meaning of Section 1 of the Human Rights Act 1998.

[Optional NIHR clauses]

12.14 [Safeguarding Provisions]

12.14.1 All Parties shall take all reasonable steps to comply with the “NIHR Policy on Preventing Harm in Research” and “NIHR Safeguarding Guidance” as published from time to time but not limited to:

- a) taking all reasonable steps to prevent actual, attempted or threatened Serious Misconduct by its employees or any other persons engaged and controlled by it to perform any activities under this Agreement; and
- b) adopting robust safeguarding and whistleblowing policies and procedures to promote and support the reporting and investigation of suspected bullying, harassment, misconduct, illegal acts, Serious Misconduct, or failures to investigate any such matter; and

- c) offering regular training as appropriate to Co-Applicants and any other persons engaged and controlled by it to perform any activities under this Agreement; and
- d) taking any other Good Industry Practice measures (including any innovative solutions).

12.14.2 The Parties will enable [Lead] to comply with the requirements of Condition 34.2 of the Main Contract to notify the Funder immediately of any investigation of or proceedings against any individuals involved in the Study relating to Serious Misconduct where the Parties have knowledge of such investigation or proceedings, and shall cooperate fully and promptly with any requests of the person or body conducting such investigation or proceedings, including allowing access to necessary documents or data required, attending any meetings and providing any information requested:

12.14.3 Each Party shall, and shall use reasonable efforts to ensure that each Party, sub-contractor or any other person involved in the performance of any activities under this Agreement shall comply with all applicable laws relating to safeguarding and the protection of children and vulnerable adults including but not limited to the vetting of personnel working closely with children and vulnerable adults in accordance with the UK Safeguarding Vulnerable Groups Act 2006 (as amended).

12.14.4 In the event that the Parties fail to comply with any of this clause 12.14, the Funder reserves the right to:

- a) deem this to be a material breach and terminate this Agreement in accordance with clause 11 herein; and/or;
- b) suspend or reduce its payment of amounts due under the payment schedule in Schedule 3 this Agreement; and/or require repayment of all or part of the funding provided under this Agreement; and/or
- c) take a breach of this clause 12.14 by the Parties into account when considering future applications for funding from any Party.]

12.15 **Academic freedom:** In adherence to English law and established UK academic practice, the Parties acknowledges and accepts commitment to upholding academic freedom and free speech, free from undue influence.]

12.16 **Counterparts:** This Agreement may be signed, including by exchange of document; or in portable document format (pdf) sent by email, in any number of counterparts, each of which will constitute an original of this Agreement, and all counterparts will together constitute the same agreement. No counterpart will be effective until each Party has executed at least one counterpart.

12.17 **Survival of clauses:** Termination by notice of this Agreement by whatever means shall not affect the provisions or clauses 1, 3, 4, 5, 6, 7, 8, 9, 11 and this clause 12 hereof.

[Signatures Follow]

Signatures

SIGNED for and on behalf of **XXXXXX**:

Name:

Position:

Signature:

Date:

SIGNED for and on behalf of **XXXXXX**

Name:

Position:

Signature:

Date:

SIGNED for and on behalf of **XXXXXX**

Name:

Position:

Signature:

Date:

Schedule 1: The Research Contract

Research contract with Funder incorporated by reference.

Schedule 2: The Application

A copy of the Funder final application form is incorporated by reference.

Schedule 3: External Funding

For the avoidance of doubt, the Parties agree that under the current regulations, they do not believe that VAT is applicable upon such sums. However each Party is responsible for VAT treatment of its own invoices and of the sums it receives and manages under this Agreement and therefore VAT is inclusive. No Party may retrospectively invoice or request a distribution from [Lead] for VAT.

The Collaborating Party(ies) shall invoice the [Lead] as per the payment schedule below. The [Lead] shall pay the Collaborating Party(ies) [quarterly in arrears] within 30 days of receipt of invoices, subject always to receipt of cleared funds from the Funder. The final invoice should be sent to the [Lead] within two (2) months of the end of the Study to allow preparation of the final cost statement by the [Lead].

Invoices should be sent for the attention of:

Email:

Quoting reference:

Invoices to be accompanied by supporting documentation indicating actual evidenced expenditure and a brief description of the work which is the subject of the invoice.

[insert payment schedule here]

Schedule 4: Delegation of Duties/ Division of Responsibilities

[to be used where responsibilities are delegated to a CTU. If a CTU is not being used then this can be marked as N/A]

Schedule 5: Data Protection

[This schedule should be used where one party is the Controller, and the other parties are Processors. Where Controller/Controller or Joint Controller relationships are in place, the Lead should use their own preferred terms.]

Where a Party Processes any Personal Data for the purpose of the Study on behalf of the other Party, the provisions of this Schedule 5 will apply to them.

1. Definitions

In this Schedule 5 the following definitions shall apply in addition to the existing definitions under clause 1.1:

'Controller', 'Processor' and 'Data Subject', 'Personal Data Breach', 'Process' and 'Processing'	shall have the meaning given to those terms in the applicable Data Protection Legislation;
'Data Processing Particulars'	means, in relation to any Processing under this Agreement: (a) the subject matter and duration of the Processing; (b) the nature and purpose of the Processing; (c) the type of Personal Data being Processed; and (d) the categories of Data Subjects
'Data Subject Request'	means an actual or purported request or notice or complaint from or on behalf of a Data Subject exercising his rights under the Data Protection Legislation in relation to Personal Data including without limitation: the right of access by the Data Subject, the right to rectification, the right to erasure, the right to restriction of processing, the right to data portability and the right to object
'EU GDPR'	Means the General Data Protection Regulations (EU) 2016/679
'ICO'	means the UK Information Commissioner's Office, or any successor or replacement body from time to time.
'ICO Correspondence'	means any correspondence or communication (whether written or verbal) from the ICO in relation to the Processing of Personal Data.

‘Losses’	means all losses, fines, penalties, liabilities, damages, costs, charges, claims, amounts paid in settlement and expenses (including legal fees (on a solicitor/client basis), disbursements, costs of investigation (including forensic investigation), litigation, settlement (including ex gratia payments), judgment, interest and penalties), other professional charges and expenses, disbursements, cost of breach notification including notifications to the data subject, cost of complaints handling (including providing data subjects with credit reference checks, setting up contact centres (e.g. call centres) and making ex gratia payments), all whether arising in contract, tort (including negligence), breach of statutory duty or otherwise, and which arise as a result of breach by another Party of the terms set out in this Schedule 5.
‘Permitted Purpose’	means the purpose of the Processing as specified in the Data Processing Particulars (Appendix 1).
‘Personal Data’	means any Personal Data (as defined in the Data Protection Legislation) processed by any Party in connection with this Agreement.
‘Personnel’	means all persons engaged or employed from time to time by the collaborating Party in connection with this Agreement, including employees, consultants, contractors and permitted agents.
‘Security Requirements’	means the requirements regarding the security of Personal Data, as set out in the Data Protection Legislation as applicable, specifically, the Data Security and Protection Toolkit.
‘Third Party Request’	means a written request from any third party for disclosure of Personal Data where compliance with such a request is required or purported to be required by law or regulation.

2. Data Protection

2.1 Arrangement Between The Parties

- 2.1.1 The Parties shall each Process the Personal Data. The Parties acknowledge that the factual arrangements between them dictate the classification of each Party in respect of the Data Protection Legislation. [Lead] shall act as the Controller and the Collaborating Parties shall act as the Processor, as follows:

- (a) [Lead] shall be a Controller where it is Processing Personal Data in relation to all data collected in the Study described in Appendix 1; and
 - (b) Each Collaborating Party shall be a Data Processor where it is Processing Personal Data in relation to the Permitted Purpose in connection with the performance of its obligations under this Agreement.
- 2.1.2 Each of the Parties acknowledges and agrees that Appendix 1 to this Schedule 5 is an accurate description of the Data Processing Particulars.
- 2.1.3 Nothing within this Agreement relieves any Collaborating Party of its own direct responsibilities and liabilities under the Data Protection Legislation.
- 2.1.4 Each Party shall make due notification to the ICO or any relevant Regulator.
- 2.1.5 Each Collaborating Party undertakes to Controller that it will take all necessary steps to ensure that it operates at all times in accordance with the requirements of the Data Protection Legislation and the Collaborating Party will, at its own expense, assist the Controller in discharging its obligations under the Data Protection Legislation as more particularly detailed in this clause 0. The Collaborating Party shall not, whether by act or omission, cause the Controller to breach any of their obligations under the Data Protection Legislation.
- 2.1.6 [Lead] shall comply with its obligations under the Data Protection Legislation as Controller in accordance with Good Industry Practice and shall use reasonable efforts to render non-identifiable any data shared with any collaborating Party as far as possible without compromising the Permitted Purpose.

2.2 Data Processor Obligations

- 2.2.1 To the extent that a Collaborating Party Processes any Personal Data as a Processor for and on behalf of the Controller it shall:
 - (a) only Process the Personal Data for and on behalf of the Controller for the purposes of performing its obligations under this Agreement, and only in accordance with the terms of this Agreement and any instructions from the Controller;
 - (b) keep a record of any Processing of the Personal Data it carries out on behalf of the Controller;
 - (c) unless prohibited by law, notify the Controller immediately (and in any event within twenty-four (24) hours of becoming aware of the same) if it considers, in its opinion (acting

reasonably) that it is required by Applicable EU Law to act other than in accordance with the instructions of the Controller, including where it believes that any of the Controller instructions under clause 2.2.1(a) infringe any of the Data Protection Legislation;

- (d) take, implement and maintain appropriate technical and organisational security measures which are sufficient to comply with:
 - (i) at least the obligations imposed on the Controller by the Security Requirements;

and where requested provide to the Controller evidence of its compliance with such requirements promptly, and in any event within forty-eight (48) hours of the request;
- (e) hold the Personal Data in such a manner that it is capable of being distinguished from other data or information processed by the Collaborating Party;
- (f) within thirty (30) calendar days, where feasible, of a request from the Controller, allow its data processing facilities, procedures and documentation to be submitted for scrutiny, inspection or audit by the Controller (and/ or its representatives, including its appointed auditors) in order to ascertain compliance with the terms of this clause 0, and provide reasonable information, assistance and co-operation to the Controller , including access to relevant Personnel and/ or, on the request of the Controller , provide the Controller with written evidence of its compliance with the requirements of this clause 0;
- (g) not disclose Personal Data to a third party (including a sub-contractor) in any circumstances without the Controllers prior written consent, save in relation to Third Party Requests where the Collaborating Party is prohibited by law or regulation from notifying the Controller, in which case it shall use reasonable endeavours to advise the Controller in advance of such disclosure and in any event as soon as practicable thereafter;
- (h) promptly comply with any request from the Controller to amend, transfer or delete any Personal Data;
- (i) notify the Controller promptly (and in any event within forty-eight (48) hours) following its receipt of any Data Subject Request or ICO Correspondence and shall:

- (i) not disclose any Personal Data in response to any Data Subject Request or ICO Correspondence without first consulting with and obtaining the Controllers prior written consent; and
 - (ii) provide the Controller with all reasonable co-operation and assistance required by the Controller in relation to any such Data Subject Request or ICO Correspondence;
- (j) notify the Controller promptly (and in any event within twenty-four (24) hours) upon becoming aware of any actual or suspected, threatened or 'near miss' Personal Data Breach in relation to the Personal Data (and follow-up in writing) and shall:
 - (i) conduct or support the Controller in conducting such investigations and analysis that the Controller reasonably requires in respect of such Personal Data Breach;
 - (ii) implement any actions or remedial measures necessary to restore the security of compromised Personal Data; and
 - (iii) assist the Controller to make any notifications to the ICO and affected Data Subjects;
- (k) comply with the obligations imposed upon a Processor under the Data Protection Legislation;
- (l) use all reasonable endeavours, in accordance with Good Industry Practice, to assist the Controller to comply with the obligations imposed on the Controller by the Data Protection Legislation, including:
 - (i) compliance with the Security Requirements;
 - (ii) obligations relating to notifications required by the Data Protection Legislation to the ICO and/ or any relevant Data Subjects;
 - (iii) undertaking any data protection impact assessments (and, where required by the Data Protection Legislation, consulting with the ICO and/or any other relevant Regulator in respect of any such data protection impact assessments); and
 - (iv) Without undue delay and where feasible not later than 72 hours after having become aware of it

notify Personal Data Breaches to the ICO and/or any other relevant Regulator unless the Personal Data Breach is unlikely to result in a risk to the rights and freedoms of natural persons;

- (m) Upon the earlier of:
 - (i) termination or expiry of this Agreement (as applicable); and
 - (ii) the date on which Personal Data is no longer relevant to, or necessary for, the Permitted Purpose

the collaborating Party shall cease Processing all Personal Data and return and/ or permanently and securely destroy so that it is no longer retrievable (as directed in writing by the Controller) all Personal Data and all copies in its possession or control and, where requested by the Controller, certify that such destruction has taken place (promptly, and in any event within forty-eight (48) hours of the request) except to the extent required by Data Protection Legislation to retain the Personal Data;

- (n) not make (nor instruct or permit a third party to make) a transfer of any Personal Data to a restricted country as set out in the Data Protection Legislation except with the prior written consent of the Controller and in accordance with any terms the Controller may impose on such transfer as the Controller deems necessary to satisfy the requirements to ensure that transfers of Personal Data outside of the UK have adequate protections in place as set out in the Data Protection Legislation;

- 2.2.2 Except as otherwise provided, this Agreement does not transfer ownership of, or create any licences (implied or otherwise), in any intellectual property rights in any Personal Data.

2.3 **Personnel**

- 2.3.1 Each Party shall take all reasonable steps to ensure the reliability and integrity of any of its Personnel who shall have access to Personal Data (including, without limitation, ensuring such Personnel shall have undergone reasonable levels of training in Data Protection Legislation and in the care and handling of Personal Data).
- 2.3.2 Each Party shall only disclose Personal Data to the Study Personnel where the following conditions have been satisfied in relation to such Study Personnel:

- (a) Each Party shall have taken (and shall continue to take) all reasonable steps to ensure the reliability and integrity of each member of the Study Personnel;
- (b) each member of the Study Personnel shall have undergone reasonable levels of training in Data Protection Legislation and in the care and handling of Personal Data; and

2.4 Appointing Sub-contractors

- 2.4.1 The Collaborating Party shall not sub-contract the performance of any of its obligations under this Agreement without the prior written consent of the Controller.
- 2.4.2 Notwithstanding any consent or approval given by the Controller under clause 2.4.1 each Collaborating Party shall remain primarily liable to the Controller for the acts, errors and omissions of any sub-contractor to whom it discloses Personal Data, and shall be responsible to the Controller for the acts, errors and omissions of such sub-contractor as if they were the Collaborating Party's own acts, errors and omissions to the extent that the Collaborating Party would be liable to the Controller under this Agreement for those acts, errors and omissions.

- 2.5 Notwithstanding anything in this Agreement to the contrary, this Schedule 5 shall continue in full force and effect for so long as the Collaborating Party Processes any Personal Data.

3. Recoverable Loss

- 3.1 The provisions in clause 9 of the Agreement shall not prevent any Party from recovering any Losses it incurs arising from a breach of the Data Protection legislation as set out in this Schedule 5.

4. Indemnity

- 4.1 Each Party ("first Party") shall indemnify on demand and keep indemnified the other Parties ("second Party") from and against:
 - 4.1.1 any monetary penalties or fines levied by the ICO and/or any other Regulator on second Party;
 - 4.1.2 the costs of any investigative, corrective or compensatory action required by the ICO and/or any other Regulator, or of defending proposed or actual enforcement taken by the ICO and/or any other Regulator;
 - 4.1.3 any Losses suffered or incurred by, awarded against, or agreed to be paid by, second party pursuant to a claim, action or challenge made by a third party against second party (including by a Data Subject); and

- 4.1.4 except to the extent that Paragraphs 4.1.1 and/ or 4.1.2 and/ or 4.1.3 apply, any Losses suffered or incurred, awarded against, or agreed to be paid by, second Party,

in each case to the extent arising directly as a result of a breach by the first Party (or its sub-contractors) of the terms set out in this Schedule 5 of the Agreement and/ or their respective obligations under the Data Protection Legislation provided that second Party notifies the first Party of any action, challenge, proceedings, claim or notice that could give rise to a liability under this indemnity, consults fully with the first Party in responding to and managing the action, challenge, proceedings, claim or notice, and if requested by the first Party gives the first Party conduct of that action, challenge, proceedings, claim or notice.

Schedule 5 Appendix 1: Data Protection Particulars

Relationships	
The subject matter and duration of the Processing	Collection and processing of data for research purposes to inform direct Study outcomes and potential secondary research before data is archived for 5 years from the end of the project
The nature and purpose of the Processing	<p>Delivering the Study and conducting/supporting secondary research using Study data</p> <p>Processing includes: collection, recording, structuring, analysing, storage, retrieval, communication, dissemination, erasure, destruction, any agreed future use.</p>
The type of Personal Data being Processed	Any Personal Data needed for the proper implementation of the Study and for the Parties to meet their contractual obligations established in the Research Contract. This includes but is not limited to: name, email address, address, Pseudonymised data, health data, sensitive category data.
The categories of Data Subjects	Any information relating to an identifiable person associated with the Study who can be directly or indirectly identified in particular by reference to an identifier that is processed in the course of the Study.
Identify relevant legal basis for Sharing/Processing Article 6	Insert the Article 6 lawful basis for sharing Personal Data. You may need support from your local Information Governance Team to complete this. This may be: processing is necessary for the performance of a task carried out in the public interest
Legal basis for Sharing/Processing special categories of personal information (if shared) [i.e. health information]	Insert the Article 9 lawful basis for sharing Personal Data. You may need support from your local Information Governance Team to complete this. This may be: processing is necessary for archiving purposes in the public interest, scientific or historical research purposes
Method of Transfer	tbc

Schedule 6: Terms and Conditions relating to the transfer of samples.

1. Precedence of terms

- 1.1 These provisions will apply where one party provides Samples to the other as part of the Study.

2. Access to and use of samples

- 2.1 The Providing Party (the party providing the Samples) shall supply the Samples “as is” without any warranty as to their safety or fitness for purpose, and are supplied under ethics approval in accordance with the relevant Protocol and informed patient consent as required.
- 2.2 The Receiving Party (the party receiving the Samples) shall use the Samples solely within its own laboratory [or as agreed in writing with the Sponsor] for the Study and not for any other purpose and only with the prior written consent of the Providing Party as evidenced by the completion and signature of the 'Material Information Form for Transfer of Human Material' completed pursuant to Clause 3.4 and Appendix 1.
- 2.3 The Receiving Party shall use the Samples in accordance with good laboratory practice and with the highest standards of skill and care in full compliance with all applicable local, government and international laws, regulations and guidelines relating to health and safety, data protection, using human materials, undertaking research and the transportation, storage, tracking, use and disposal of the Samples in the UK including but not limited to the Human Tissue Act 2004.
- 2.4 In no event shall the Receiving Party use the Samples for clinical, therapeutic or diagnostic purposes, including but not limited to, *in vitro* diagnostic purposes, *ex vivo* or *in vivo* therapeutic purposes or investigational use (including use in humans or animals or in or with substances to be administered to or used or consumed by humans or animals) without the express prior written consent of the Providing Party.
- 2.5 Samples shall at all times remain the property of the [Providing Party] and shall not be removed from the Receiving Party address.
- 2.6 The Receiving Party shall keep the Samples secure [within the laboratory at its premises] and ensure that access to the Samples is restricted to the authorised workers on the Study who are bound by the terms of this Agreement.
- 2.7 The Receiving Party shall not supply the Samples to any Third Party [unless it is dictated by the Protocol].
- 2.8 The Receiving Party shall not use the Samples in any work supported by any Third Party without the prior written permission of the Providing Party which,

where granted, shall be conditional on the terms of that Third Party support not conflicting with the terms of this Agreement and any obligations that the Providing Party may have regarding the Samples.

- 2.9 The Receiving Party shall not use the Samples for any commercial purpose, including but not limited to commercially-sponsored research or work that is subject to the granting of any rights to a commercial Third Party, and shall not use or permit the use of any products or processes containing or using the Samples for profit-making or commercial purposes.
- 2.10 These terms governing the exchange and use of Samples shall not be interpreted to prevent or delay publication of research findings.
- 2.11 All matters concerning indemnity and liability relating to the transfer and use of Samples are set out in the main body of the Agreement.

Schedule 6: Material information form for transfer of human material

The following information shall be completed by the Parties prior to any transfer of Samples comprising human biological material pursuant to this Agreement.

Please detail the following arrangements for all human biological material taken:

1) The nature and quantity of the materials in question:

[To be completed by the Parties]

2) The reason that the material is being taken:

[To be completed by the Parties]

3) Where the material is to be sent:

[To be completed by the Parties]

4) How long the samples will be stored for:

[To be completed by the Parties]

5) What will happen to any remaining material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction):

[To be completed by the Parties]

Or

N/A – No samples comprising human biological material shall be transferred.